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Syed

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(54) **APPARATUS AND METHOD FOR A BIFURCATED CATHETER FOR USE IN HOSTILE AORTIC ARCHES**

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(51) **Int. Cl.**

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A61F 2/962	(2013.01)

(52) **U.S. Cl.**

CPC ***A61F 2/954*** (2013.01); ***A61F 2/962*** (2013.01)

(58) **Field of Classification Search**

CPC .. A61F 2/954; A61F 2/962; A61F 2/95; A61F 2/958; A61F 2017/1205; A61F 2002/9517; A61F 2/02; A61F 2/04; A61B 17/12022; A61B 17/32056; A61B 2002/9517; A61B 17/12118

USPC 606/108

See application file for complete search history.

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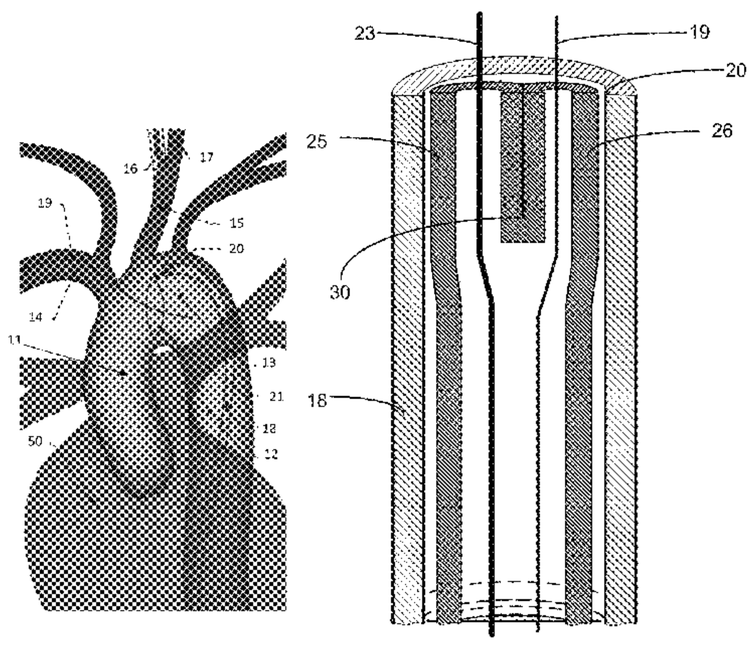
(57) **ABSTRACT**

Systems and methods for addressing the percutaneous intervention related trauma to the vessels that arise from type-III hostile aortic arches, from uncontrolled prolapse of sheaths, embolic protection devices and stent delivery systems, by stabilizing the systems while stenting of the left and right carotid arteries. Guide wires to stabilize catheters used to access the left or right carotid arteries (CA) for carotid percutaneous intervention of the vessels originating from a tortuous aortic arch are disclosed. A bifurcated catheter for stabilizing the catheters is also disclosed. The bifurcated catheter has a main catheter that divides into two separate catheters forming a "Y" shape. One leg of the catheter has a smaller diameter with a smaller working lumen (inner diameter) to carry the stabilizing wire and the other leg of the catheter has a larger working lumen for arterial stenting operations.

24 Claims, 12 Drawing Sheets



Cross section of the bifurcated catheter within the sheath catheter close to the point of bifurcation (Not to scale)

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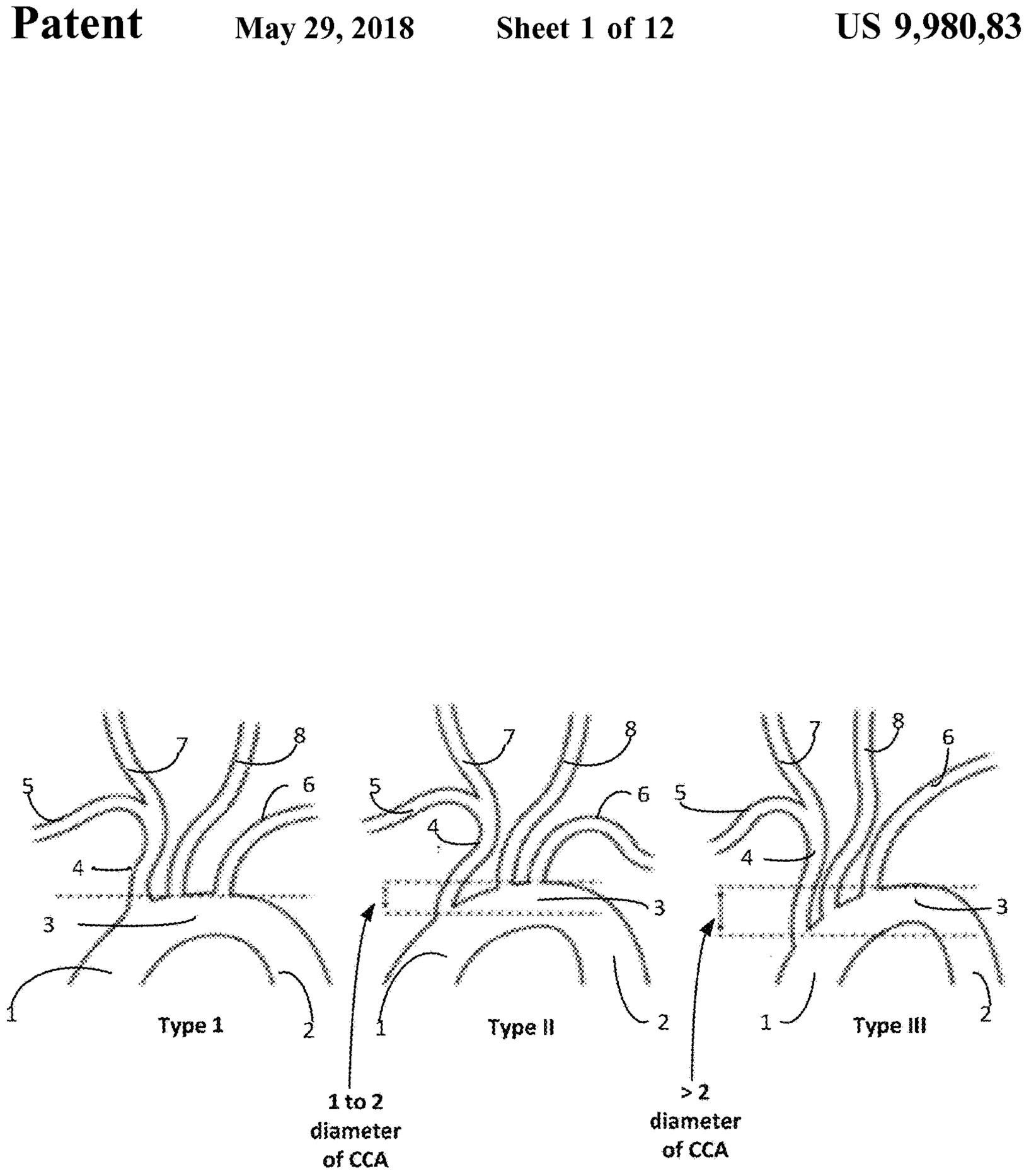
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Type II
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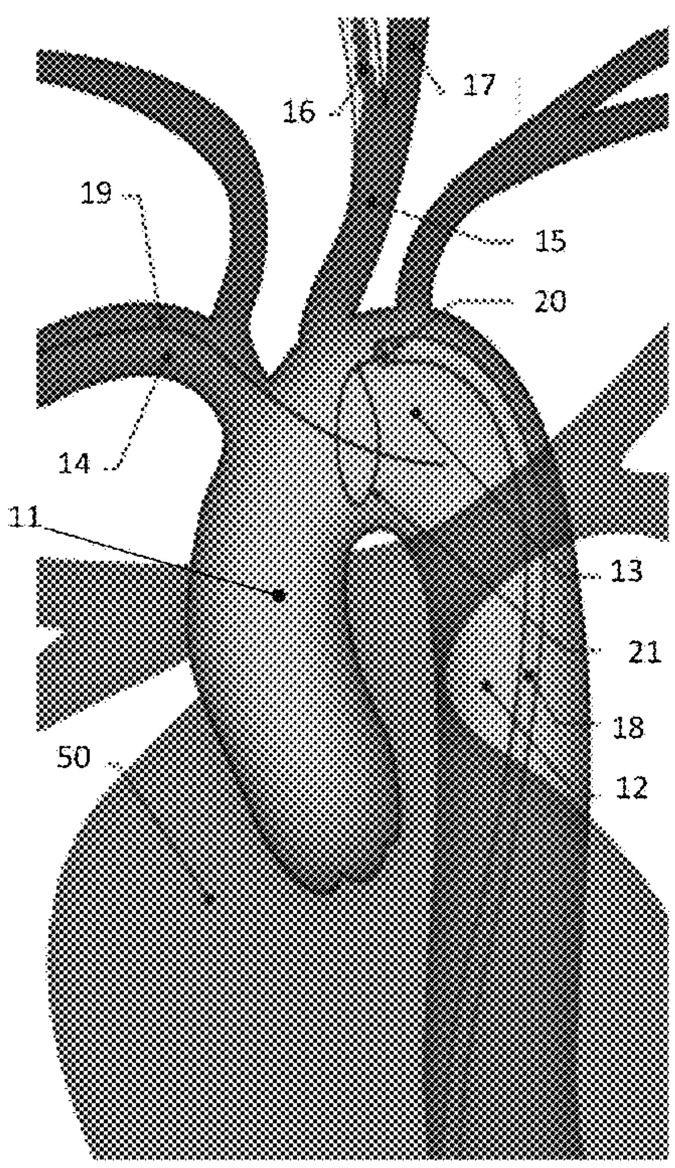
Figure 1



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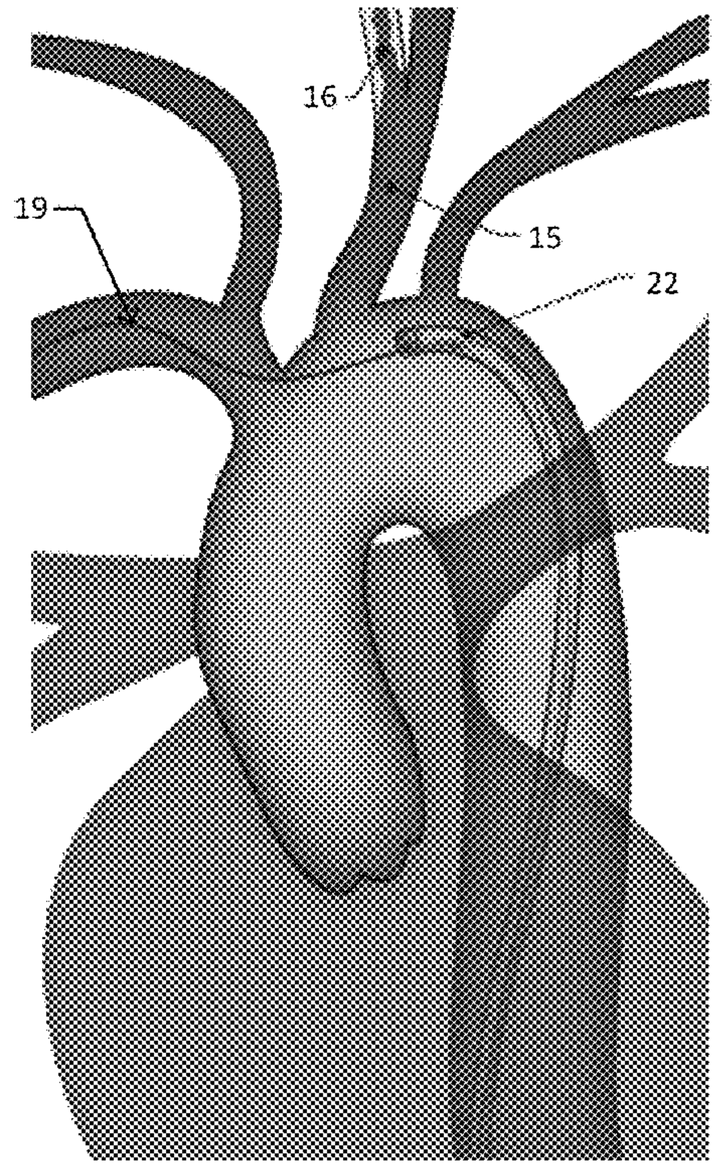

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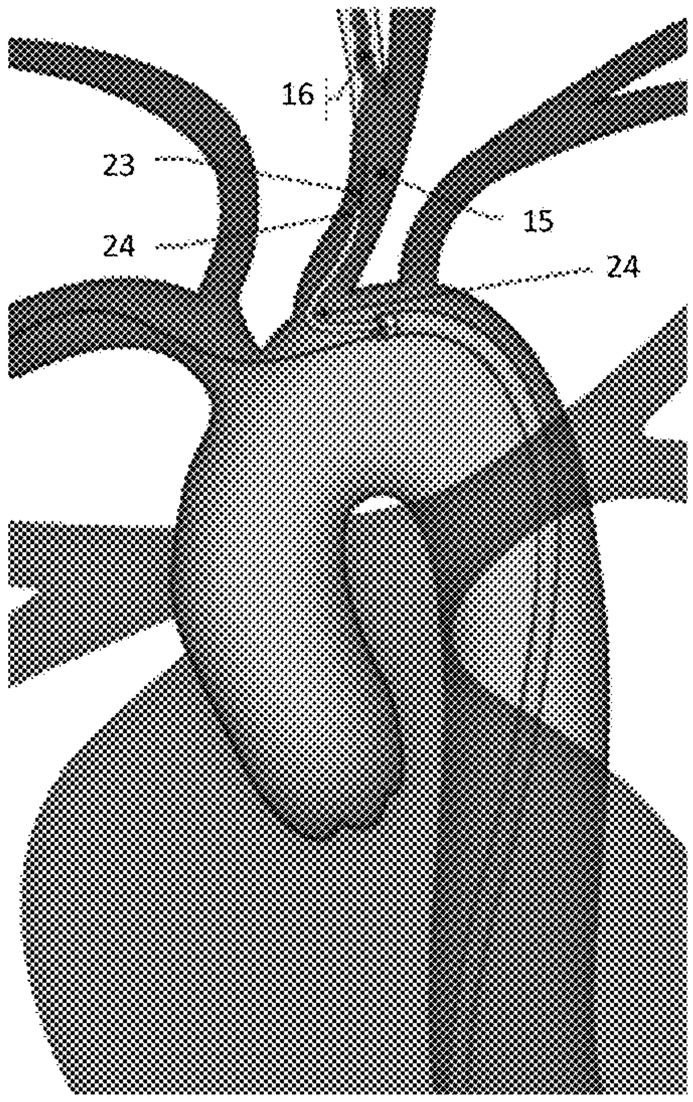

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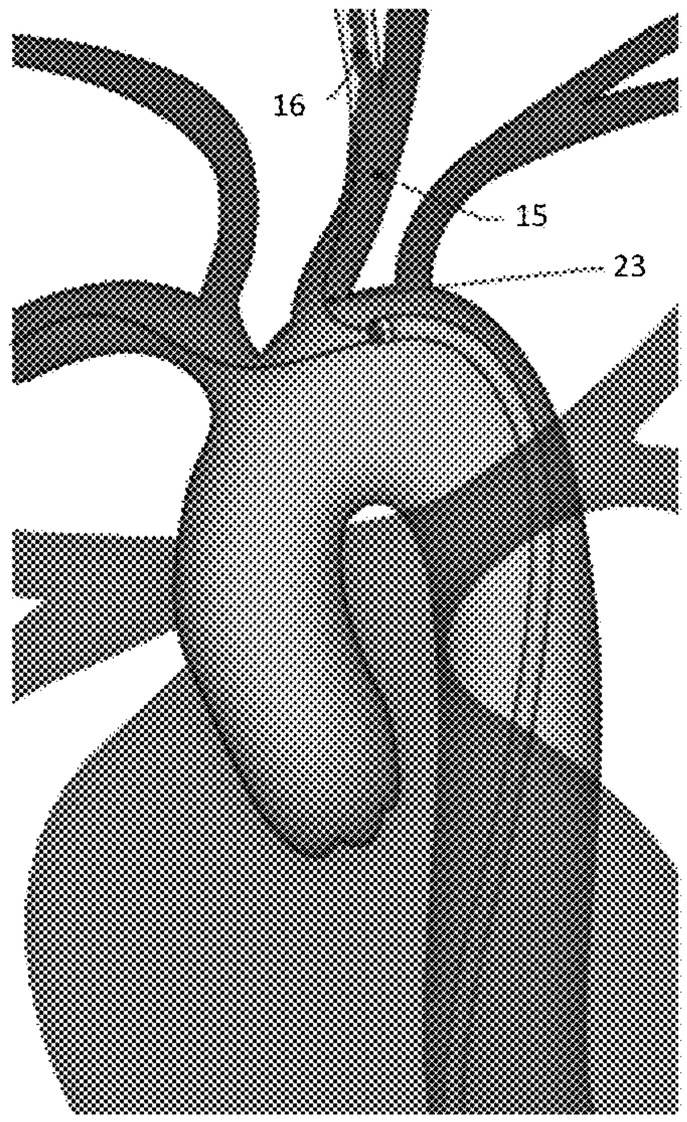

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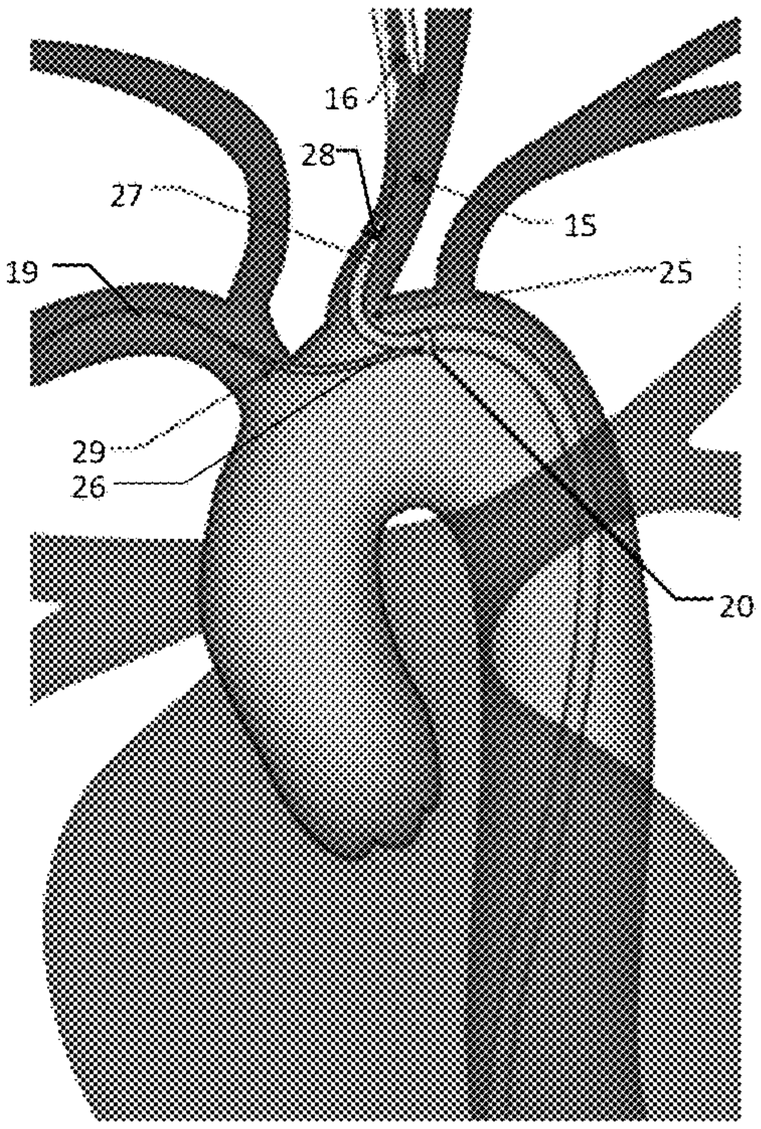


Figure 6

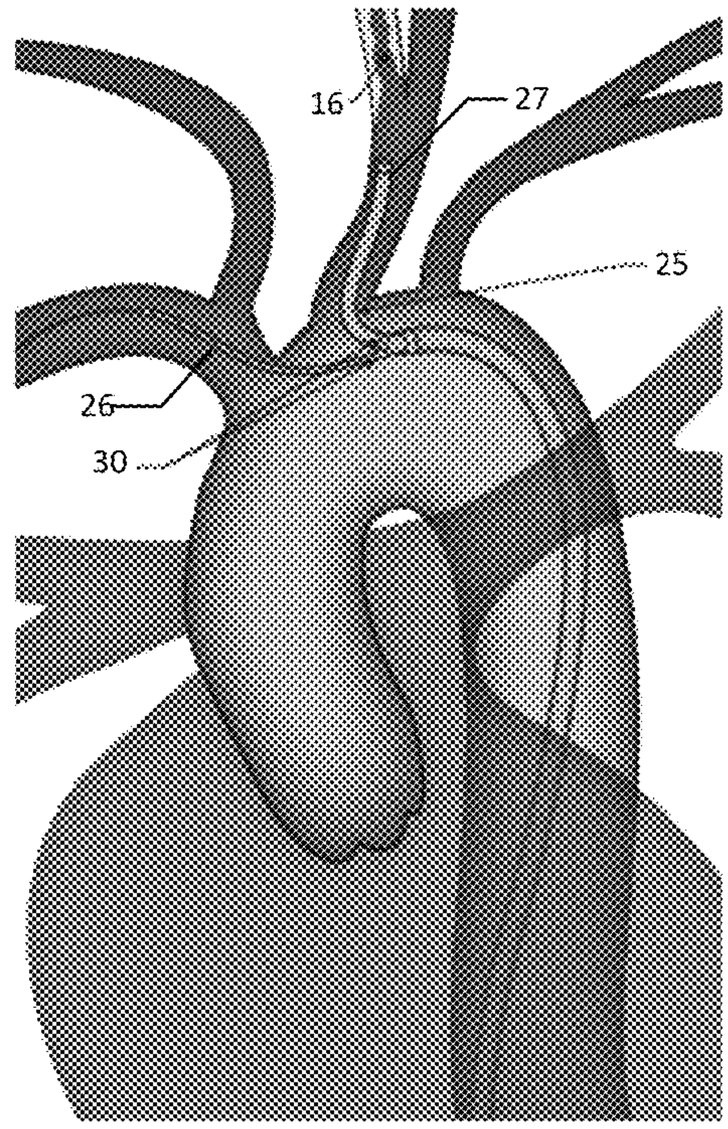


Figure 7

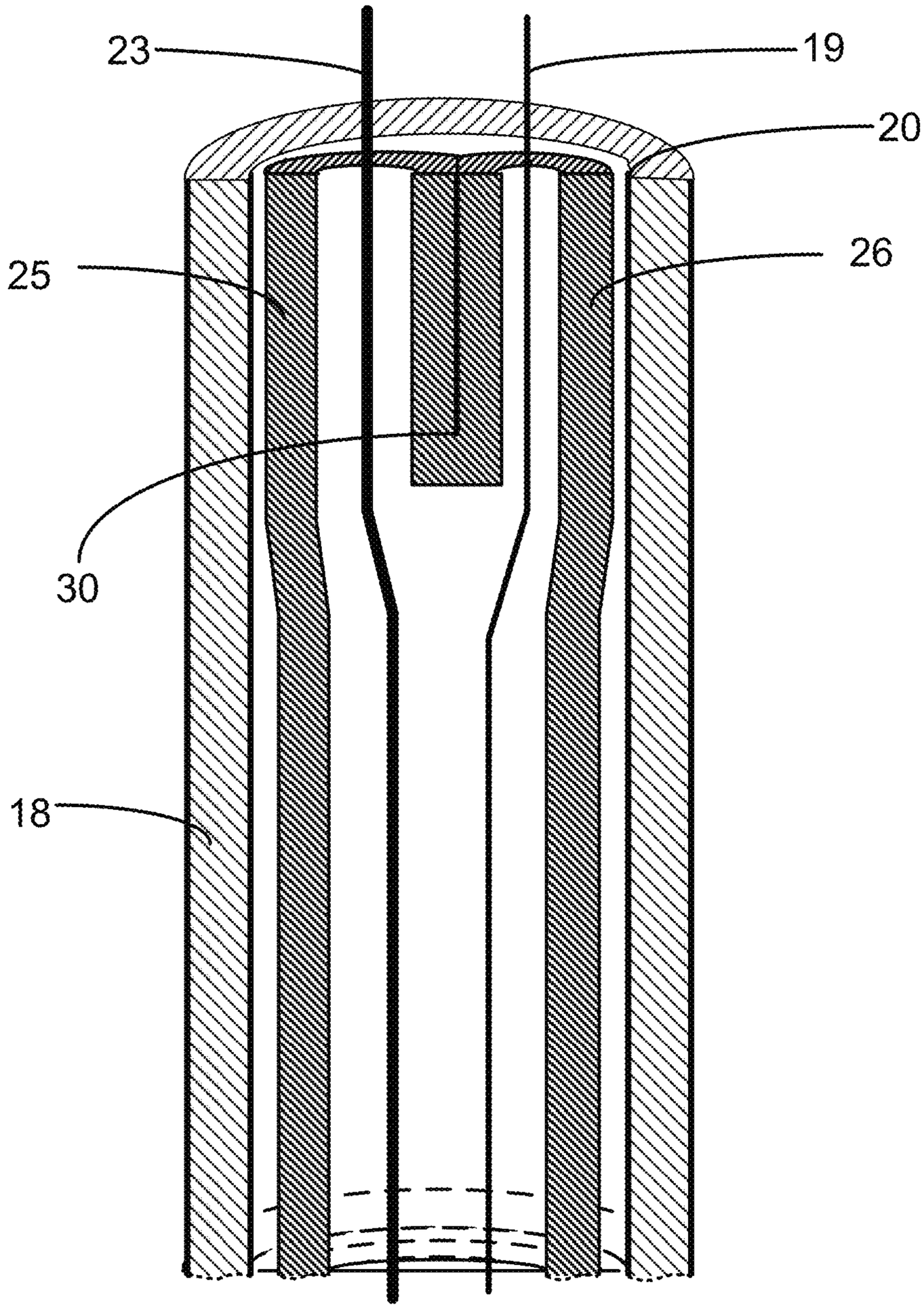


Figure 6 A

Cross section of the bifurcated catheter within the sheath catheter close to the point of bifurcation (Not to scale)

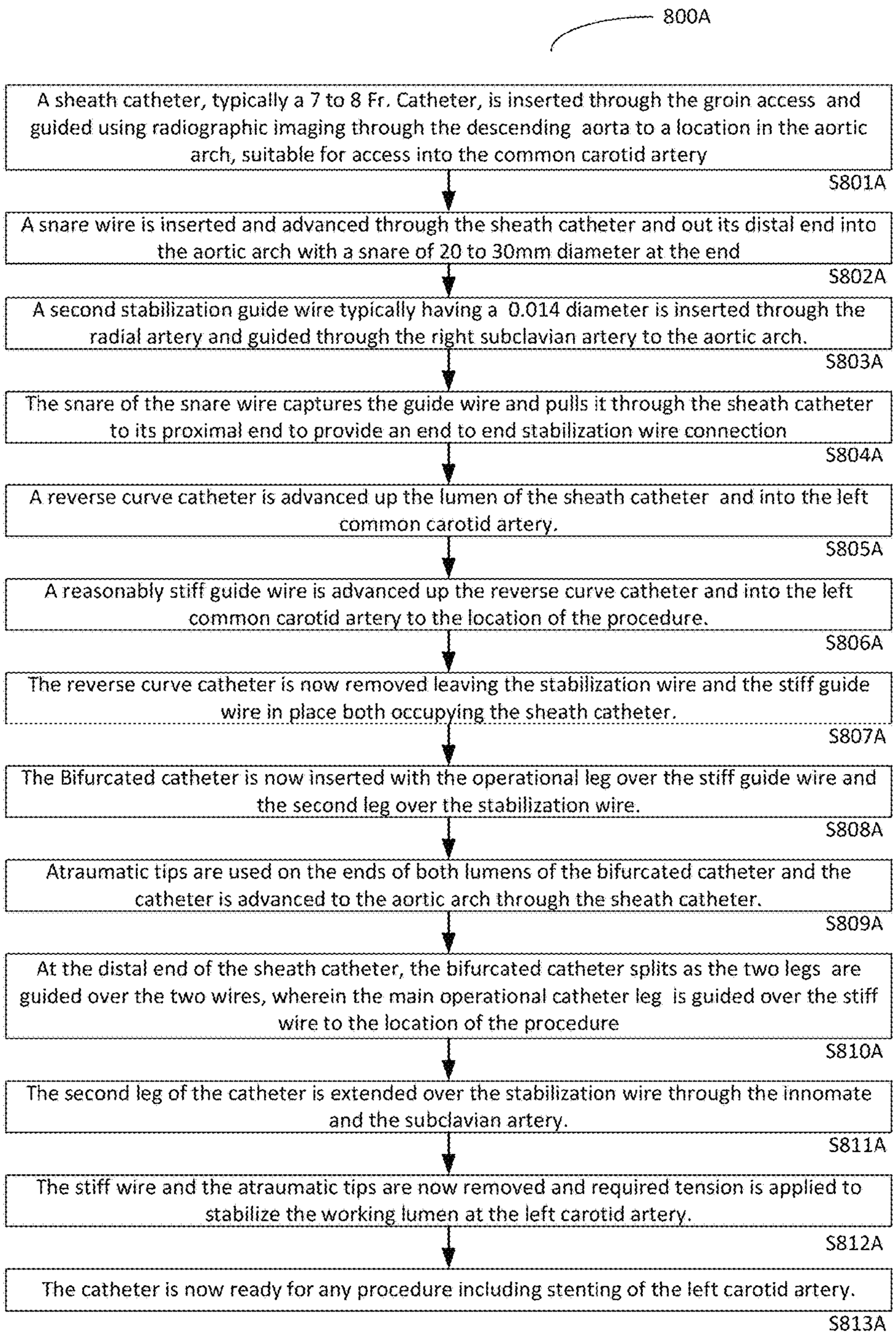

800A
A sheath catheter, typically a 7 to 8 Fr. Catheter, is inserted through the groin access and guided using radiographic imaging through the descending aorta to a location in the aortic arch, suitable for access into the common carotid artery
S801A
A snare wire is inserted and advanced through the sheath catheter and out its distal end into the aortic arch with a snare of 20 to 30mm diameter at the end
S802A
A second stabilization guide wire typically having a 0.014 diameter is inserted through the radial artery and guided through the right subclavian artery to the aortic arch.
S803A
The snare of the snare wire captures the guide wire and pulls it through the sheath catheter to its proximal end to provide an end to end stabilization wire connection
S804A
A reverse curve catheter is advanced up the lumen of the sheath catheter and into the left common carotid artery.
S805A
A reasonably stiff guide wire is advanced up the reverse curve catheter and into the left common carotid artery to the location of the procedure.
S806A
The reverse curve catheter is now removed leaving the stabilization wire and the stiff guide wire in place both occupying the sheath catheter.
S807A
The Bifurcated catheter is now inserted with the operational leg over the stiff guide wire and the second leg over the stabilization wire.
S808A
Atraumatic tips are used on the ends of both lumens of the bifurcated catheter and the catheter is advanced to the aortic arch through the sheath catheter.
S809A
At the distal end of the sheath catheter, the bifurcated catheter splits as the two legs are guided over the two wires, wherein the main operational catheter leg is guided over the stiff wire to the location of the procedure
S810A
The second leg of the catheter is extended over the stabilization wire through the innomate and the subclavian artery.
S811A
The stiff wire and the atraumatic tips are now removed and required tension is applied to stabilize the working lumen at the left carotid artery.
S812A
The catheter is now ready for any procedure including stenting of the left carotid artery.
S813A

Figure 8A

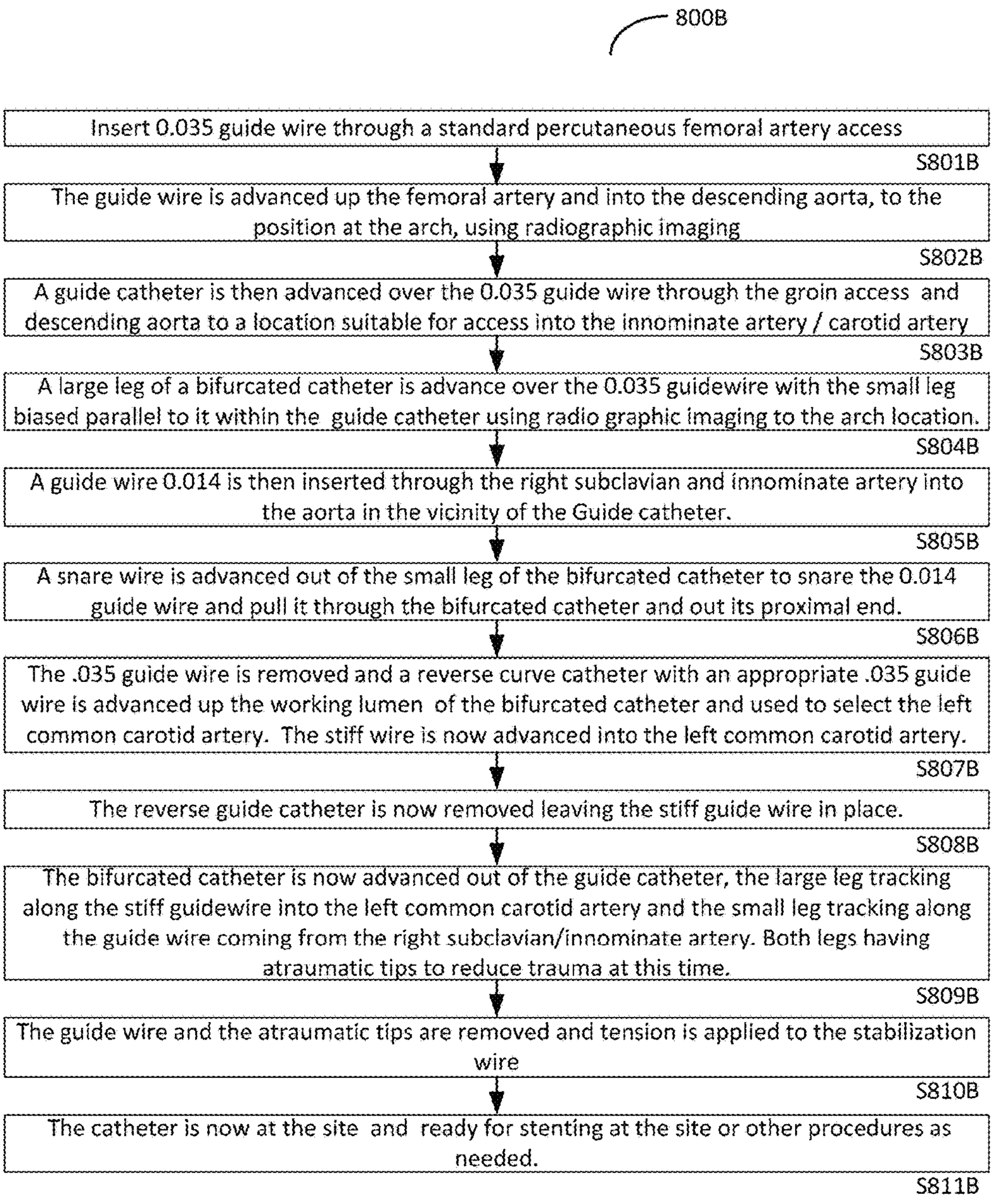
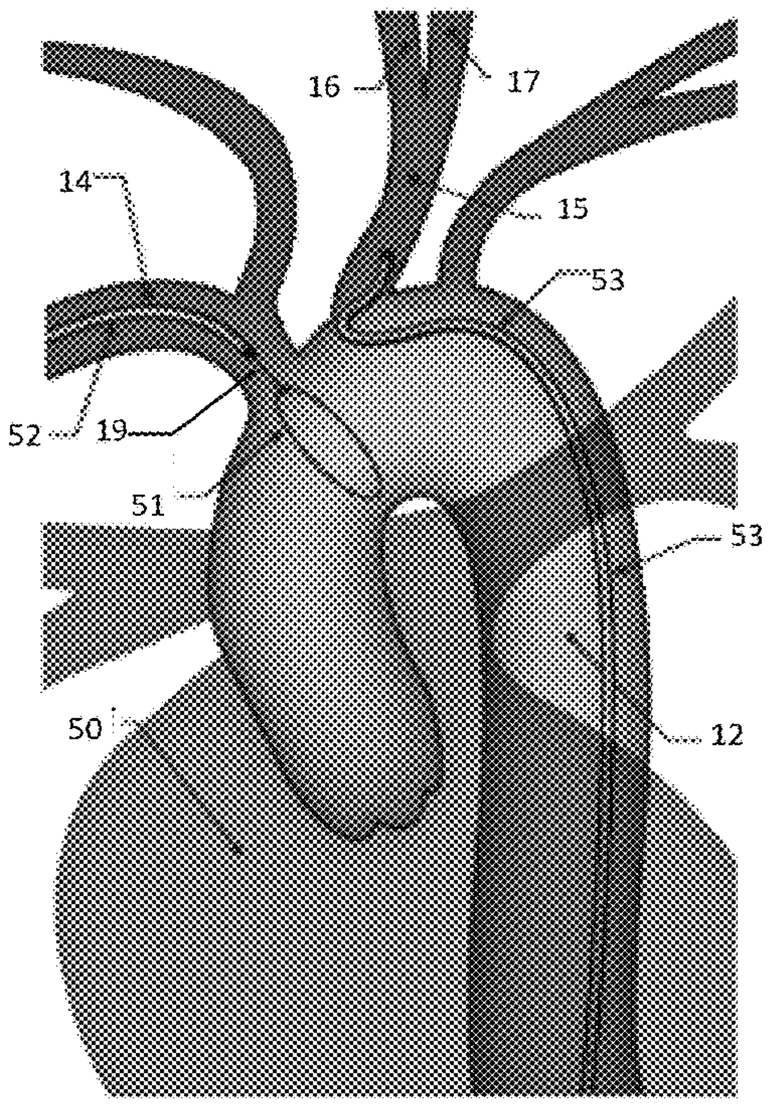

800B
Insert 0.035 guide wire through a standard percutaneous femoral artery access
S801B
The guide wire is advanced up the femoral artery and into the descending aorta, to the position at the arch, using radiographic imaging
S802B
A guide catheter is then advanced over the 0.035 guide wire through the groin access and descending aorta to a location suitable for access into the innominate artery / carotid artery
S803B
A large leg of a bifurcated catheter is advance over the 0.035 guidewire with the small leg biased parallel to it within the guide catheter using radio graphic imaging to the arch location.
S804B
A guide wire 0.014 is then inserted through the right subclavian and innominate artery into the aorta in the vicinity of the Guide catheter.
S805B
A snare wire is advanced out of the small leg of the bifurcated catheter to snare the 0.014 guide wire and pull it through the bifurcated catheter and out its proximal end.
S806B
The .035 guide wire is removed and a reverse curve catheter with an appropriate .035 guide wire is advanced up the working lumen of the bifurcated catheter and used to select the left common carotid artery. The stiff wire is now advanced into the left common carotid artery.
S807B
The reverse guide catheter is now removed leaving the stiff guide wire in place.
S808B
The bifurcated catheter is now advanced out of the guide catheter, the large leg tracking along the stiff guidewire into the left common carotid artery and the small leg tracking along the guide wire coming from the right subclavian/innominate artery. Both legs having atraumatic tips to reduce trauma at this time.
S809B
The guide wire and the atraumatic tips are removed and tension is applied to the stabilization wire
S810B
The catheter is now at the site and ready for stenting at the site or other procedures as needed.
S811B

Figure 8 B



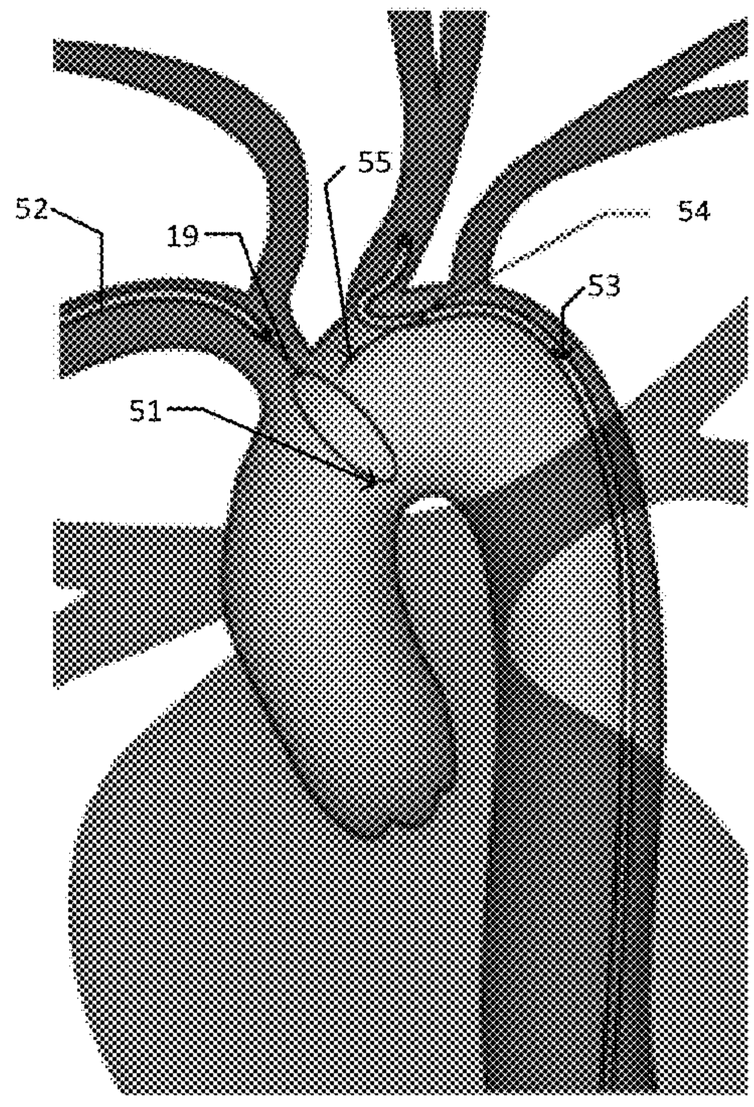
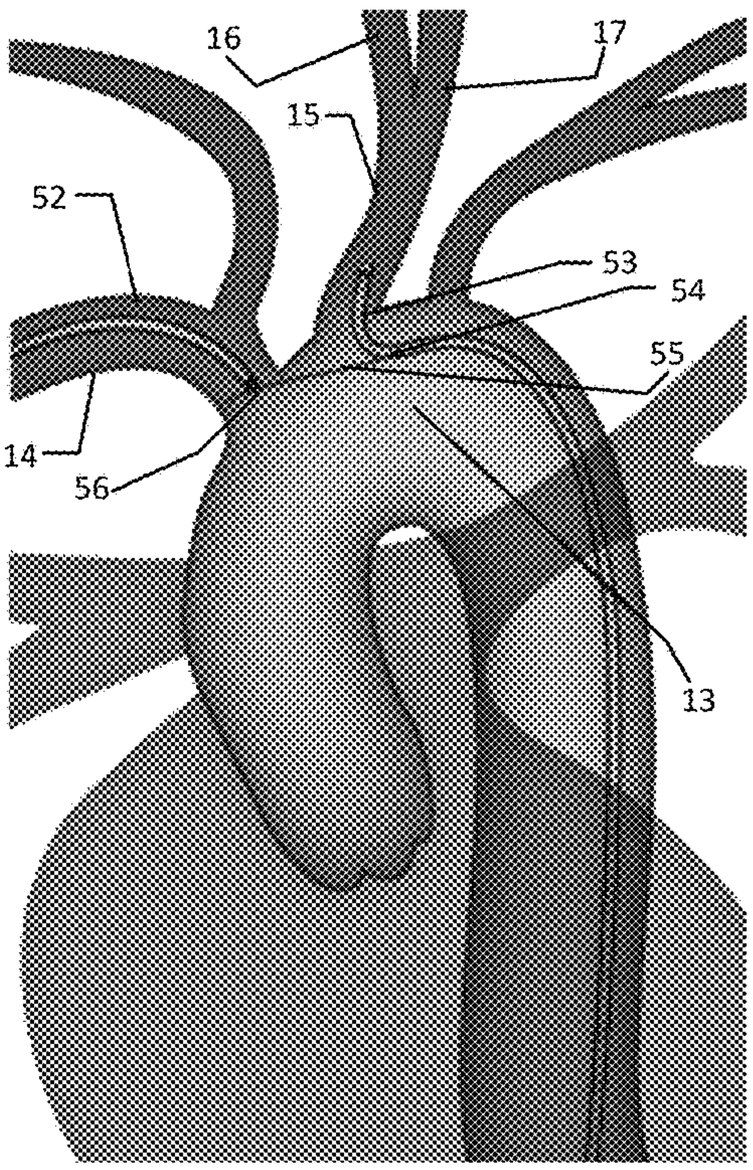


Figure 9

Figure 10



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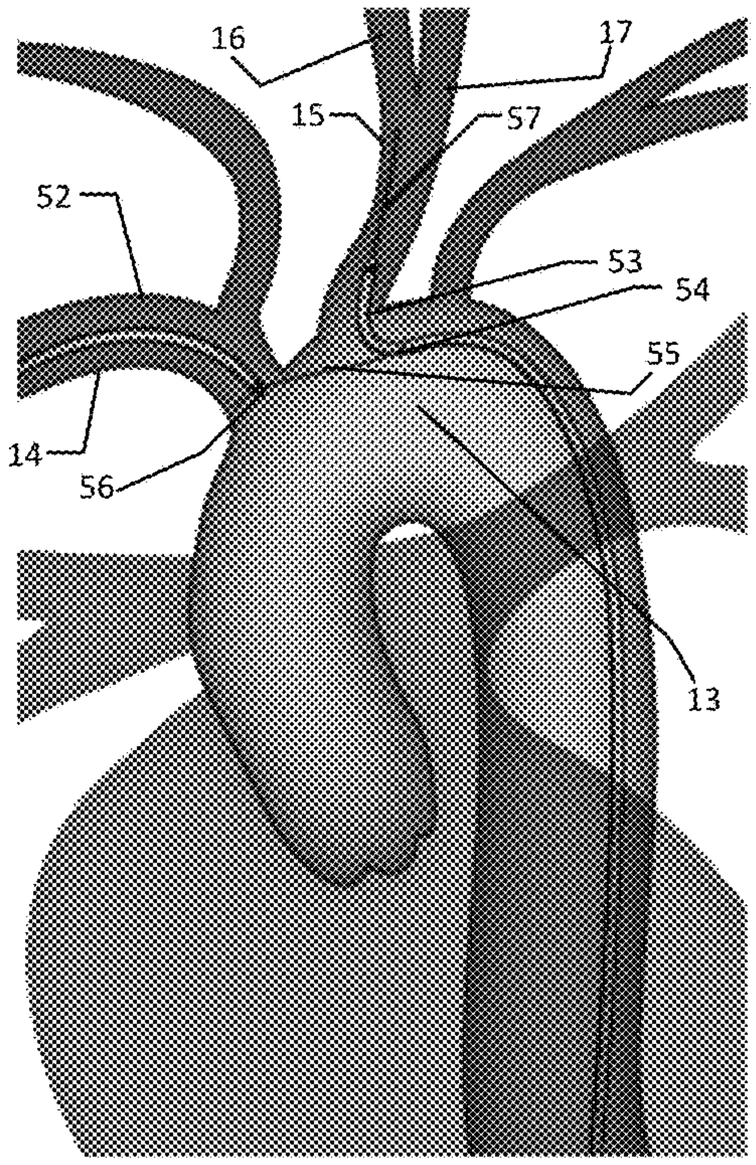

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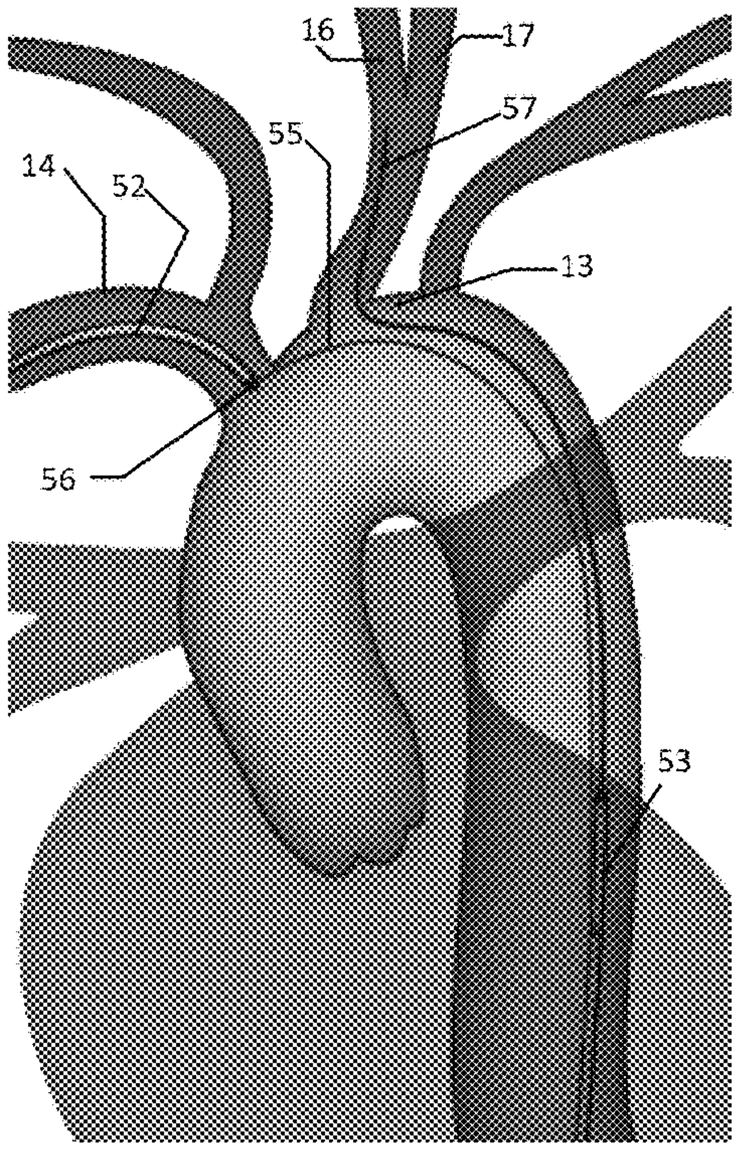

Figure 13

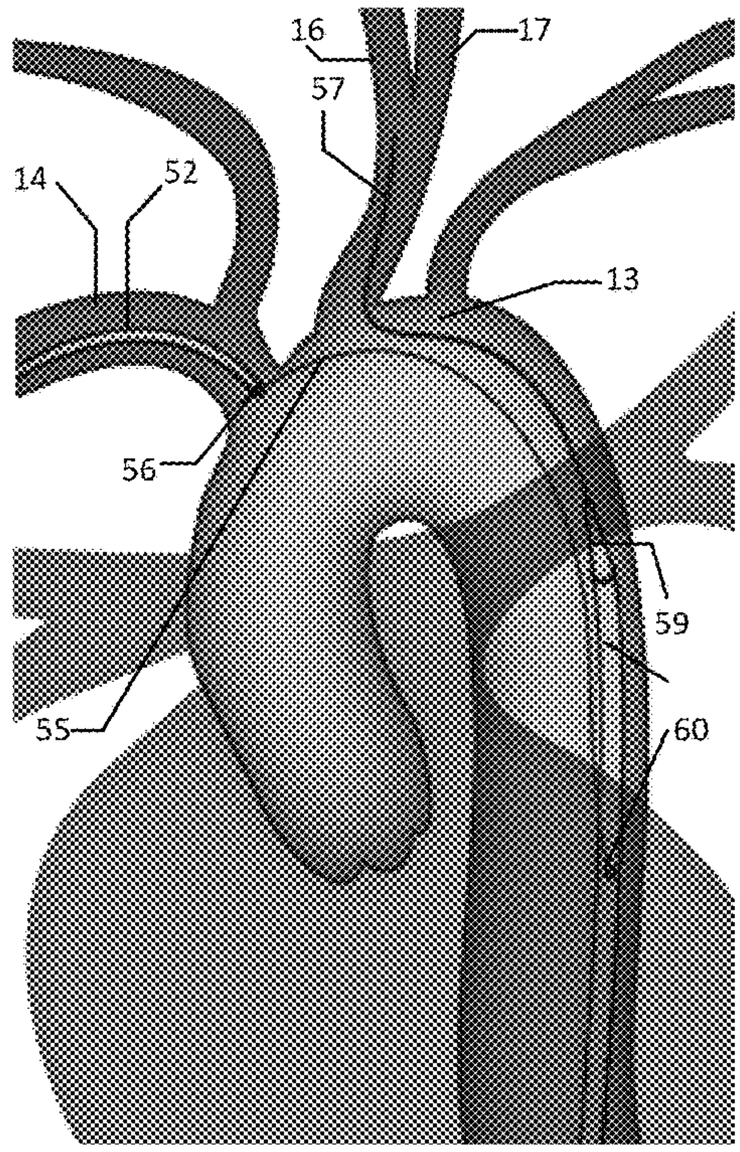

Figure 14

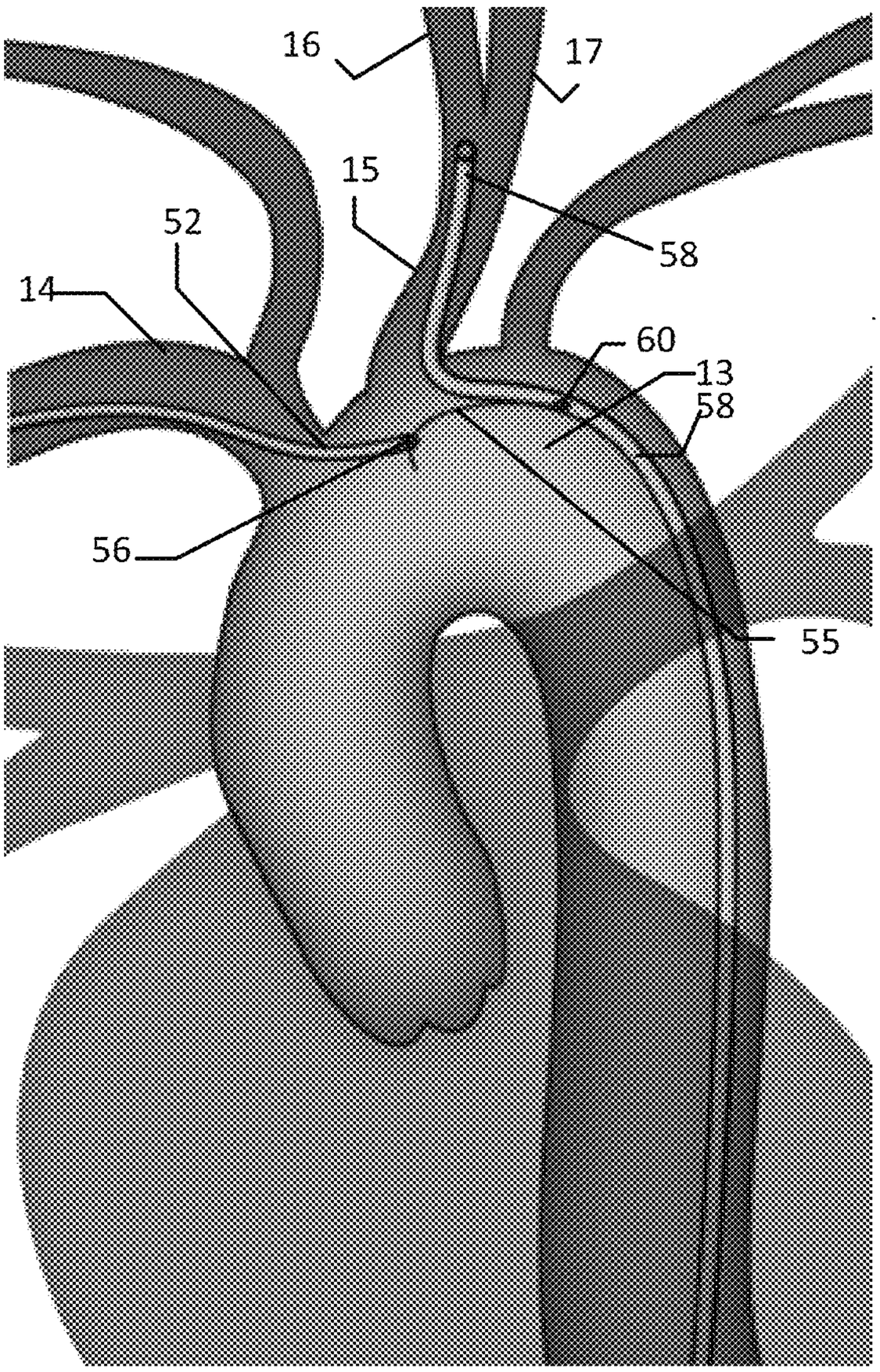

Figure 15

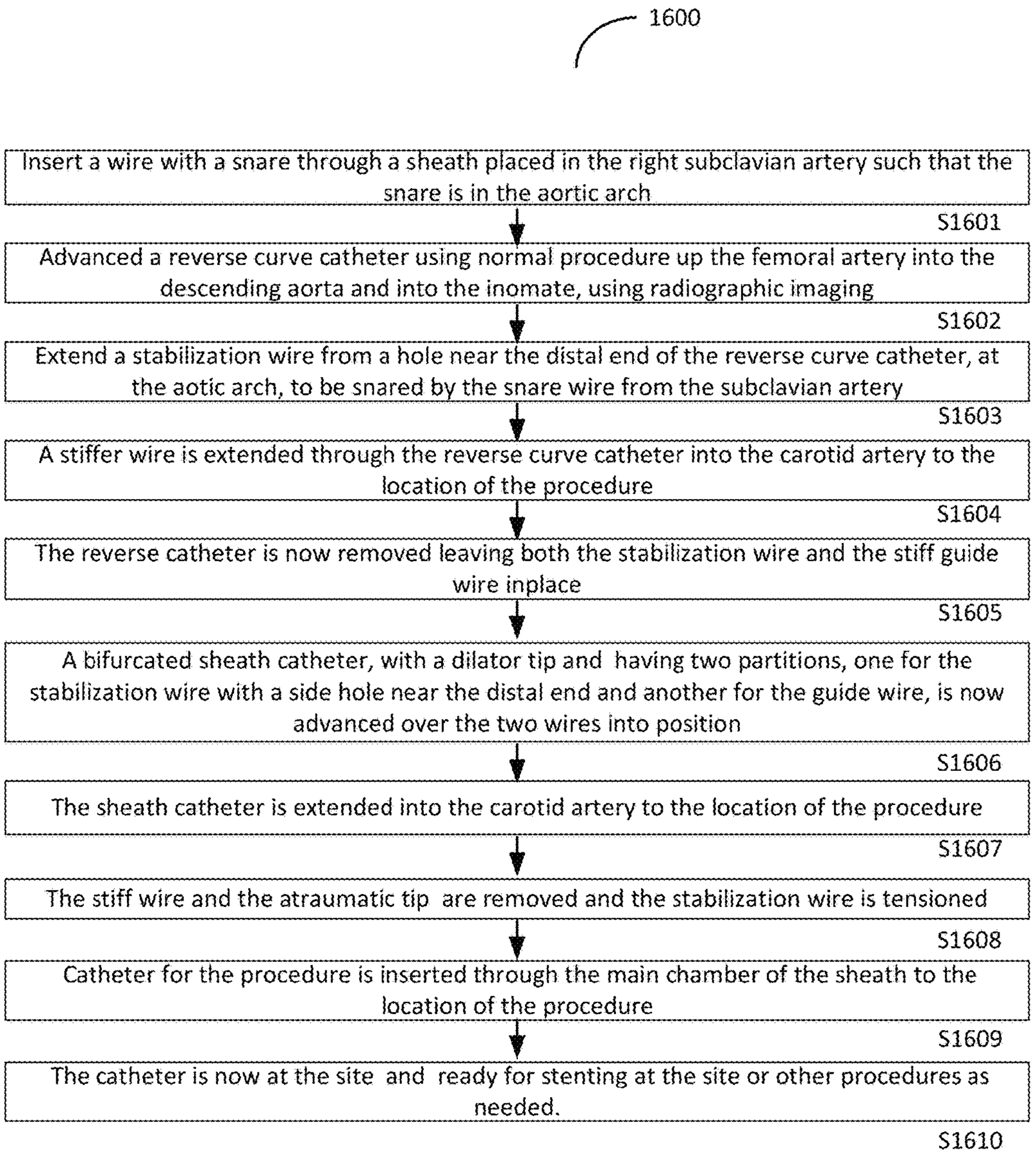
1600
Insert a wire with a snare through a sheath placed in the right subclavian artery such that the snare is in the aortic arch
S1601
Advanced a reverse curve catheter using normal procedure up the femoral artery into the descending aorta and into the inomate, using radiographic imaging
S1602
Extend a stabilization wire from a hole near the distal end of the reverse curve catheter, at the aotic arch, to be snared by the snare wire from the subclavian artery
S1603
A stiffer wire is extended through the reverse curve catheter into the carotid artery to the location of the procedure
S1604
The reverse catheter is now removed leaving both the stabilization wire and the stiff guide wire inplace
S1605
A bifurcated sheath catheter, with a dilator tip and having two partitions, one for the stabilization wire with a side hole near the distal end and another for the guide wire, is now advanced over the two wires into position
S1606
The sheath catheter is extended into the carotid artery to the location of the procedure
S1607
The stiff wire and the atraumatic tip are removed and the stabilization wire is tensioned
S1608
Catheter for the procedure is inserted through the main chamber of the sheath to the location of the procedure
S1609
The catheter is now at the site and ready for stenting at the site or other procedures as needed.
S1610

Figure 16

APPARATUS AND METHOD FOR A BIFURCATED CATHETER FOR USE IN HOSTILE AORTIC ARCHES

BACKGROUND

1. Field

The invention relates to improved methods and apparatus used in catheter based interventional procedures, mainly involving type II and III hostile aortic arches, and the access and deployment of stents in the carotid arteries and procedures above the neck.

2. Related Art

Stenting of the carotid artery (CA) is relatively new to interventional procedures. It is a challenging procedure because accessing the left or right carotid artery can be dependent on the anatomical disposition of the aortic arch.

FIG. **1** illustrates the aortic arch. As shown in FIG. **1**, the a aorta **1** includes an aortic arch region **3**, a descending aorta **2**, and an innominate **4**. Three types of arches shown in FIG. **1**: Type I, Type II and Type III arches. Also shown in FIG. **1** is the right subclavian artery (RSA) **5**, left subclavian artery (LSA) **6**, right common carotid artery (RCCA) **7** and left common carotid artery (LCCA) **8**.

The arch types are defined by the height of the top of the aortic arch **3** from the base location where the innominate **4** attaches to the aorta. In a type I arch, the height is less than the diameter of the common carotid artery (CCA). Similarly, in a type II arch, the height of the top of the arch **3** from the base of the innominate **4** is of the order of 1 to 2 times the diameter of the CCA. In a type III arch, the height is more than twice the diameter of the CCA. As the height of the arch increases the procedures within the carotid arteries become more and more difficult due to the tortuous nature of the arterial connections to the aorta at the arch.

In type III hostile aortic arches, the arch itself can be very acute thus making the access of the left or right carotid arteries ostium difficult. Subsequent placement of a stent delivery system in a stable mode into the arterial system above it therefore becomes more difficult. The stenting procedure itself is meant to re-establish a more normalized blood flow through the carotid and internal carotid artery into the brain by opening up regions of the artery constricted by plaque deposits which inhibit flow. The stents themselves can be self-expanding, balloon expandable, bio-absorbable, and/or covered. The stent delivery systems are designed to accommodate very acute bends but are reliant upon the guide catheter and guide wires and or embolic protection devices to stabilize them during deployment. Stents have been used to open "stenosis"—semi-occluded sections of the arterial system—for many years. They come in a wide variety and are designed for specific areas of the body, these include: balloon expandable, self-expanding, covered and bio-absorbable stents. Stenting in the neck and procedures above the neck are challenging when confronted with a type III hostile aorta, in particular stenting of the left or right carotid artery. During the insertion, manipulation and stabilization of the stent delivery mechanism and during removal of the guide wire and secondary wire, injuries to the subclavian artery and the tortuous aortic arch can happen. This can be caused by uncontrolled collapse of the sheath, embolic protection device (EPD) and stent/stent delivery system in the ascending aorta during procedure. This type of prolapse can result in the patient suffering cerebral embolism or stroke by dragging the fully deployed EPD over the carotid stenosis. Further, dragging the guide wires over the tortuous arterial regions can cause cutting into the arterial

walls or otherwise injuring the artery resulting in dissections and trauma to the vessels involved. These traumas can be dangerous to the patient as they can ultimately directly affect blood flow by leakage at the dissections or by creating accumulation of thrombus, an organization of blood cells, which is a natural reaction to vessel injury. These may require additional procedures to repair and heal the damaged artery walls and prevent problems.

Accordingly, what is needed is systems and methods to stabilize the sheath, the EPD and the stent delivery system within the carotid arterial system to reduce the injuries caused to the arterial walls during stenting and other minimally invasive treatment of the carotid arteries and above the neck procedures.

SUMMARY

The following summary of the invention is included in order to provide a basic understanding of some aspects and features of the invention. This summary is not an extensive overview of the invention and as such it is not intended to particularly identify key or critical elements of the invention or to delineate the scope of the invention. Its sole purpose is to present some concepts of the invention in a simplified form as a prelude to the more detailed description that is presented below.

In accordance with one aspect of the invention, a carotid percutaneous intervention system is disclosed that includes a sheath catheter percutaneously insertable and positionable in an aortic arch; a guidewire deliverable through percutaneous femoral artery access; and a stabilization wire comprising a snare slideably inserted through the sheath catheter, the stabilization wire configured to snare the guidewire and pull a portion of the guidewire within the sheath catheter.

The system may further include a reverse curve catheter insertable through the sheath catheter parallel to the stabilization wire.

The system may further include a stiff guidewire insertable through the reverse curve catheter.

The system may further include a bifurcated catheter inserted through the sheath catheter over the stabilization wire.

The bifurcation catheter may include a common catheter portion at a proximal end of the bifurcation catheter; a first leg at a distal end of the bifurcation catheter, wherein the first leg is deliverable over the stiff wire to a treatment site; and a second leg at a distal end of the bifurcation catheter, wherein the second leg is positionable over the stabilization wire, wherein the first leg and the second leg join with the common catheter portion at a junction. The junction may be Y-shaped.

The bifurcated catheter may be pre-loaded into the sheath catheter.

The bifurcated catheter may include a procedural lumen and a stabilization lumen. The procedural lumen may extend from the proximal end through the common catheter to the distal end through the first leg, and the stabilization lumen may extend from the proximal end through the common catheter to the distal end through the second leg. The stabilization lumen may be for slideably receiving a snare catheter and the stabilization wire.

A distal tip of the first leg and a distal tip of the second leg may include atraumatic tips.

The system may further include a procedural catheter insertable through the first leg of the bifurcated catheter.

The stabilization wire may be further configured to snare the guidewire and pull a portion of the guidewire within the bifurcated catheter.

The stabilization wire may be configured to pull the guide wire through a proximal end of the sheath.

Tension may be applicable to the ensnared guidewire and stabilization wire to stabilize the system.

In accordance with another aspect of the invention, a carotid percutaneous intervention system is disclosed that includes a sheath catheter percutaneously insertable and positionable in an aortic arch; a wire comprising a snare slideably inserted the sheath catheter; a reverse curve catheter advanceable into an innominate, the reverse curve catheter comprising a proximal end and a distal end and including a hole near the distal end; a stabilization wire extendable from the hole of the reverse curve catheter at the aortic arch, wherein the wire comprising the snare is configured to snare the stabilization wire and pull a portion of the stabilization wire within the sheath catheter.

The system may further include a stiff guidewire insertable through the reverse curve catheter and at the treatment site in the carotid artery.

The reverse curve catheter may be removable following delivery of the stiff guidewire in the carotid artery.

The system may further include a bifurcated catheter insertable over the stabilization wire and the stiff guidewire into the carotid artery.

The bifurcation catheter may include a common catheter portion at a proximal end of the bifurcation catheter; a first leg at a distal end of the bifurcation catheter, wherein the first leg is deliverable over the stiff wire to a treatment site; and a second leg at a distal end of the bifurcation catheter, wherein the second leg is positionable over the stabilization wire, wherein the first leg and the second leg join with the common catheter portion at a junction. The junction may be Y-shaped.

The bifurcated catheter may include a procedural lumen and a stabilization lumen.

The system may further include a procedural catheter insertable through the bifurcated catheter after removal of the stiff guidewire.

In accordance with yet another aspect of the invention, a bifurcated catheter for use in a carotid percutaneous intervention system is disclosed that includes a body comprising a proximal end and a distal end, wherein the body includes a common catheter portion at the proximal end; a first leg at the distal end; and a second leg at a distal end, wherein the first leg and the second leg join with the common catheter portion at a junction.

The junction may be Y-shaped.

The body may include a procedural lumen and a stabilization lumen that extend from the proximal end to the distal end of the body.

The procedural lumen may extend from the proximal end through the common catheter to the distal end through the first leg, and the stabilization lumen may extend from the proximal end through the common catheter to the distal end through the second leg.

The stabilization lumen may be for slideably receiving a stabilization wire.

A distal tip of the first leg and a distal tip of the second leg may include atraumatic tips.

The bifurcated catheter may reduce trauma to the vessels while providing stabilization to a process catheter for procedures within a carotid arterial system.

The bifurcated catheter may protect a right innominate, carotid artery and subclavian artery of a patient during manipulation of a guide wire.

In accordance with a further aspect of the invention, a method for carotid percutaneous intervention is disclosed that includes advancing a guidewire to the aortic arch using radiographic imaging; advancing a sheath catheter over the guidewire to the descending aorta; advancing a snare wire to the aortic arch; ensnaring the guidewire with the snare wire to form a stabilization wire and pulling the stabilization wire into the sheath catheter.

The snare wire may be advanced out of a small leg of a bifurcated catheter and the snare wire may pull the stabilization wire through the bifurcated catheter.

The guidewire may be pulled through a proximal end of the bifurcated catheter.

The method may further include inserting the guidewire through percutaneous femoral artery access.

The method may further include advancing a reverse guide catheter and second guidewire up an operational lumen of the bifurcated catheter into a common carotid artery, wherein the second guidewire is stiffer than the guidewire.

The method may further include removing the reverse guide wire after delivering the second guidewire.

The method may further include advancing the bifurcated catheter such that the operational lumen of the bifurcated catheter advances over the second guidewire to a treatment site.

The method may further include removing the second guidewire and performing a treatment operation at the treatment site.

The method may further include advancing a reverse curve catheter into the descending aorta, and wherein the guidewire extends through a hole near a distal end of the reverse curve catheter.

The method may further include delivering a second guidewire into the carotid artery and removing the reverse curve catheter.

The method may further include delivering a bifurcated catheter to a treatment site.

The bifurcated catheter may include a stabilization lumen and an operational lumen, and wherein delivering the bifurcated catheter to the treatment site may include advancing the stabilization lumen over the stabilization wire and advancing the operational lumen over the second guidewire.

The method may further include removing the second guidewire and performing a treatment operation at the treatment site.

The method may further include applying tension to the stabilization wire.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated into and constitute a part of this specification, illustrate one or more examples of embodiments and, together with the description of example embodiments, serve to explain the principles and implementations of the embodiments.

FIG. **1** is a schematic diagram illustrate the three types of aortic arches encountered in humans.

FIG. **2** is a schematic diagram illustrating a distal end of a device with a snare wire extended from the main guide catheter capturing a stabilization wire from the subclavian artery (SA) in accordance with one embodiment of the invention.

FIG. **3** is a schematic diagram illustrating the aortic arch with a stabilization guide wire snared and pulled into the main guide catheter and out the proximal end in accordance with one embodiment of the invention. The bifurcated catheter may or may not be at this stage located just inside the distal tip of the main guide catheter. The bifurcated catheter in one embodiment may be advanced over the wire after step S**808**A (FIG. **8**A) while in another embodiment the bifurcated catheter may be pre-loaded at the distal tip of the main guide catheter (FIG. **8**B).

FIG. **4** is a schematic diagram illustrating a reverse curve diagnostic catheter with a guide wire coming out of in the distal tip of the main guide catheter and up into the left common carotid artery in accordance with one embodiment of the invention. In one embodiment, the reverse curve diagnostic catheter with the guide wire is extended out of the sheath or the main guide catheter, and in another embodiment, the bifurcated catheter is at the distal tip of the main guide catheter and the reverse curve diagnostic catheter with the guide wire comes out of the larger leg of the bifurcated catheter.

FIG. **5** is a schematic diagram illustrating removal of a reverse curve diagnostic catheter, leaving behind a stiff guide wire in the left common carotid artery in accordance with one embodiment of the invention.

FIG. **6** is a schematic diagram illustrating a bifurcated catheter being advanced out of a main guide catheter over respective guide wires, the large leg over the stiff guide wire into the left common carotid artery and the small leg being advanced over the guide wire into the right subclavian artery in accordance with one embodiment of the invention.

FIG. **6**A is a cross-sectional view of a portion of the bifurcated catheter in accordance with one embodiment of the invention.

FIG. **7** is a schematic diagram of the legs of the bifurcated catheter advanced out of the main guide catheter and parked into their respective vessels in accordance with one embodiment of the invention. In some embodiments, the atraumatic tips are removed from each leg and the stabilized catheter is ready for procedures.

FIG. **8**A is a flow chart of a procedure for stabilizing the process catheter and stenting systems in accordance with one embodiment of the invention.

FIG. **8**B is a flow chart of a procedure for stabilizing the process and stent catheters in which one of bifurcations of the pre-loaded bifurcated catheter is used to accommodate the snare/stabilization catheter in accordance with one embodiment of the invention.

FIG. **9** is a schematic diagram showing the snare wire extended from a protective sheath through the subclavian artery (AS) in accordance with one embodiment of the invention.

FIG. **10** is a schematic diagram showing a wire extended out of a side hole of the initial reverse curve diagnostic catheter to be captured by the snare in accordance with one embodiment of the invention.

FIG. **11** is a schematic diagram illustrating capturing the stabilization wire by the snare wire loop in accordance with one embodiment of the invention.

FIG. **12** is a schematic diagram of the extension of a stiff guide wire from the reverse curve Simmons catheter into the carotid artery in accordance with one embodiment of the invention.

FIG. **13** is a schematic diagram showing the removal of the reverse catheter leaving the guide wire and the stabilization wire in place in accordance with one embodiment of the invention.

FIG. **14** is a schematic diagram of the working sheath catheter, having an atraumatic tip and the working sheath catheter having a second chamber for the guide wire extending out of a side hole, being advanced over the guide wire in accordance with one embodiment of the invention.

FIG. **15** is a schematic diagram of the working sheath catheter advanced to the location of the procedure and the guide wire removed in readiness for a procedure in accordance with one embodiment of the invention.

FIG. **16** is a flow diagram for stabilizing the process catheters and systems in accordance with one embodiment of the invention.

DETAILED DESCRIPTION

Embodiments of the invention are directed to new devices and associated methods for the placement of stents in the carotid artery, and especially into the left or right carotid arteries, for procedures above the neck. These new devices and associated methods stabilize the working lumen or delivery sheath for the carotid stent delivery system. These new devices and associated methods also protect the innominate and subclavian artery as well as the aortic arch from trauma during stenting and other procedures above the neck where there is a possibility for trauma to the arteries as a result of tension on the secondary or stabilization guidewire. This is especially true in the case of patients with type II and Type III aortic arch.

Embodiments of the invention are directed to the application and use of guide wires for stabilization of the catheters used to access the left or right carotid arteries (CA) for carotid percutaneous intervention of the vessels originating from a tortuous aortic arch.

Embodiments of the invention use a bifurcated catheter having a main catheter arm that is used to extend into the region of the procedure and a support catheter arm that extends into the right subclavian artery to provide protection to that vessel during tightening of a support and stabilization wire through the right subclavian artery. The head of a sheath/guide catheter is at that time placed in the aorta, at the branching of either innominate or the left or right carotid artery through which the procedural arm of the bifurcated catheter, that is the second branch of the bifurcated catheter, has to be extended to conduct the procedure or place the stent. The correct placement of the head of the sheath catheter and the extension of the support catheter to cover the support wire enable the wires to be extended and retracted without damage to the arch and the arterial vessels used during procedure.

In some embodiments, the bifurcated catheter includes a main catheter that divides into two separate catheters forming a "Y" shape. One leg of the bifurcated catheter has a smaller diameter with a smaller working lumen (inner diameter) to carry the stabilizing wire and the second leg of the bifurcated catheter has a larger working lumen for arterial stenting operations/procedures. This bifurcated catheter addresses the percutaneous intervention related trauma to the vessels that arise from type-II or type-III hostile aortic arches, from uncontrolled prolapse of the sheath, embolic protection device and stent delivery system, by stabilizing the systems, using a through-and-through stabilization wire for applying tension during stenting of the left and right carotid arteries.

In one embodiment, a sheath catheter is percutaneously inserted at the groin and directed through the descending aorta to the aortic arch. A snare is inserted through the sheath and linked with a 0.014 inch or 0.018 inch guide wire from

the right subclavian artery (via the right radial or brachial artery access) to provide a stabilization wire for the operational catheter. At this stage, the stabilization wire and the main guide wire occupy the sheath catheter. A reverse curve catheter is then inserted through the sheath catheter over the main guide wire, parallel to the stabilization wire and guided to the common carotid artery from the aortic arch. A stiff guide wire is then inserted through the reverse catheter to the location of the procedure. The reverse curve catheter is then removed leaving the guide wire in the location of the procedure. The bifurcated catheter is then guided to the aortic arch with one stabilization leg over the stabilization wire and the other operational leg over the stiff guide wire such that the operational leg is guided into the common carotid artery while the stabilization leg is guided over the stabilization wire into the subclavian artery. The stiff guide wire is then removed leaving the operational leg of the bifurcated catheter in place for treatment procedures.

In one embodiment, a secondary stabilization wire having a small diameter, e.g., 0.014 or 0.016 inch, is guided through a, for example, Fr-3 or Fr-5, micro sheath, which is placed percutaneously through the right radial or brachial artery and threaded through the subclavian artery and snared into the main guide catheter to stabilize the distal tip. This way, the tension can be applied to the distal tip of the guide catheter to stabilize it in a more planar orientation by putting tension on the stabilization wire, as discussed above, to aid in the stabilization of the guide catheter, which is placed under fluoroscopy (C Arm) in the aorta using percutaneous access. This secondary stabilization wire is hence inserted into the right radial or brachial artery and guided through the right subclavian artery and down and out of the guide catheter. Though the description is provided for the secondary access via the right radial of brachial artery, it should not be considered limiting. It is possible to provide the secondary access via the left radial or brachial artery, external carotid artery or common carotid artery (instead of just the right radial or brachial artery). It may also be possible to have more than one accessory access to complete the procedure using the device. Once the stabilization wire is established, a tension is applied to one or both ends of the secondary stabilization wire to help stabilize the distal end of the guide catheter during the accessing of the left or right internal carotid artery. This allows the stent delivery system to track more easily through the acute anatomy of the arch, especially one such as a type III arch.

In another embodiment, the bifurcated catheter is preloaded into the end of the main guide catheter or long sheath. In this embodiment, the bifurcated catheter has a procedural lumen and a second lumen that can accommodate a snare catheter and wire. It will be appreciated, however, that a potential disadvantage of this device is that the catheter will need to be a bigger device to accommodate the two lumens, but the advantage is that it separates the wires from the beginning so that the wires do not inadvertently wrap around each other during the procedure and cause problems. In this embodiment, the guide catheter is provided with a bifurcated distal configuration having two legs in the form of a Y at the distal end. One leg is of a large diameter, typically having an inner diameter or "working lumen" sufficient to allow the passage of a stent delivery system or other therapeutic devices. The second leg is of a smaller diameter than the first leg with an inner diameter sufficient to accept a snare wire and snare the stabilization guide wire. This bifurcated catheter is sized so as to fit easily through the main guide catheter placed at the start of the procedure and is of sufficient length so as to allow the main leg of the bifurcated catheter to be placed into the carotid artery for stenting and other procedures there and above the neck. The secondary leg is of sufficient length so as to be placed over a stabilization wire from the right subclavian artery and cover it sufficiently to prevent damage to the vessels it passes through while providing the necessary stabilization to the main guide catheter and the bifurcated catheter, during procedural manipulations. Both legs of the bifurcated catheter need not be of the same stiffness or durometer to be able to navigate their respective vessels. For instances the main carotid leg may be of a lesser durometer so as to navigate the arch into the selected carotid artery without affecting the natural anatomic configuration whereas the small leg may be stiffer so as to help with the stabilization of the main guide catheter.

In one embodiment, another practical device and method for safely accessing the carotid artery is disclosed. In this a first reverse curve catheter is inserted percutaneously and directed into the right or left common carotid artery (RCCA or LCCA). A secondary wire is inserted in the reverse curve catheter and out of a hole in the catheter at the location of the arch to be captured by a snare wire that is extended out of a protective sheath extended through the subclavian artery (typically via right radial artery access). Once the snare has captured the stabilization wire a more rigid guide wire is extended through the reverse catheter into the common carotid artery towards the location of the procedure. The reverse catheter is then removed leaving both the rigid guide wire and the stabilization wire in place. A sheath/procedural catheter with a conical atraumatic tip and also having therein a second chamber with a hole close to the distal end for providing an exit for the stabilization wire is advanced over the guide wire and stabilization wires to the aortic arch and the sheath catheter is extended on to the location of procedure. Tension is applied to the stabilization wire for providing support to any working catheter that is inserted through the sheath catheter after removal of the stiff guide wire for conducting the procedure as needed.

In some embodiments, a sheath cover may be used for the stabilization wire as it extends into the subclavian artery when tension is applied prevent unwanted damage to the artery. The stabilized main sheath helps the procedure to be completed and the operational catheter and the sheath catheter to be removed safely.

In some embodiments, a reverse curve guide catheter with a lumen large enough for stenting is used to select the common carotid artery. A secondary wire is inserted in the reverse curve catheter through a parallel lumen in the reverse curve catheter and out of a hole in the catheter at the location of the arch. This secondary wire is then captured by a snare wire with a loop that is extended out of a protective sheath extended through the subclavian artery, typically inserted via right radial artery access. The carotid stenting procedure can now proceed in the standard way described above since the reverse curve guiding catheter itself is stabilized and is usable for procedure.

In percutaneous procedures of the vessels originating from a tortuous aortic arch, the use of stabilization wires in addition to guide wires to guide and stabilize the delivery catheters used to access the left or right carotid arteries is disclosed. The need for the stabilization of the sheath, the embolic protection device (EPD) and the stent delivery system (SDS) is to prevent the uncontrolled prolapse of the sheath, EPD and SDD during stenting procedure in the ascending aorta. This type of prolapse can result in cerebral embolism or stroke in patients by the dragging of the fully deployed EPD across critical carotid internal artery stenosis. Embodiments of the invention provide for stabilizing the

sheath, the EPD and the SDS within the left or right carotid arteries by providing a secondary stabilization wire that holds the primary sheath in place within the tortuous aortic arch during the procedure, thereby providing the necessary stability for the SDS within the carotid artery during the procedure. These stabilizing wires typically originate from a low profile radial or brachial artery access and provide a through-and-through tension and support to the sheath by enabling the application of tension to one or either end of the stabilization wire through a typical micro-sheath or catheter. In this embodiment the brachial artery or a small radial artery is usable with the micro-sheath, and similarly in the case of another embodiment described the sheath catheter is used to puncture the radial artery or the brachial artery for entry, to provide adequate hemostasis while keeping the entry profile low. In one embodiment, the stabilization wire has a small diameter, e.g., 0.014 or 0.018 inch diameter, the micro-sheath has a 3 Fr. Diameter, and the sheath catheter has a 5 Fr. Diameter. The use of the small size wire and micro-sheath is useful in preventing hematoma in the brachial artery, which can be devastating in patients receiving anticoagulation drugs, such as Heparin, and anti-platelet therapy such as Plavix, during or after the procedure. The stabilizing wire from the brachial artery enters the aortic arch through the right subclavian artery to be captured and brought out through the sheath at its proximal end. Due to their diameter and forces applied during the procedures, the guide wires, if used without proper covering can inadvertently cause trauma to the associated tortuous vessels walls. The bifurcated catheter disclosed herein provides the necessary protection to the arch and the subclavian artery while providing the necessary stabilization to the sheath, SDS and EPD for access and procedures within the carotid arteries, especially for above the neck procedures. The bifurcated catheter disclosed includes a main catheter that divides into two separate catheters forming a "Y" shape. One leg of the catheter has a smaller diameter with a smaller working lumen (inner diameter), to carry the stabilizing wire, than the second leg of the catheter that has a larger working lumen for arterial stenting operations. This device provides the necessary stability to the system for stenting of the carotid arteries while addressing the percutaneous intervention related trauma to the vessels associated with type-III hostile aortic arches that arise therefrom. Multiple embodiments of the invention are described here under. Even though in the examples described the secondary access is shown as being established via the right radial or brachial artery, it should not be considered limiting in any way. The secondary access may be established via any of the left radial or brachial artery, external carotid artery or common carotid artery (instead of just the right radial or brachial artery). It may also be possible to have more than one accessory access to complete the procedure using the device.

A first embodiment of the invention is described with reference to the schematic diagrams shown in FIGS. **2** to **7** and the flow chart of FIG. **8**A. This embodiment illustrates the ability to conduct procedures such as stenting in the left internal carotid artery (LICA) **16** using a procedural catheter that can be inserted through the aortic arch **13** and left common carotid artery **15**.

As shown in FIG. **2**, a sheath catheter **18** is initially inserted percutaneously and guided using fluoroscopic tracking using the opaque metal ring **20** at its distal end. In one embodiment, the sheath catheter **18** is a 7 French (Fr) or 8 Fr sheath; it will be appreciated that differently sized sheath catheters may be used as known to those of skill in the art. The sheath **18** is guided through the femoral artery and the descending thoracic aorta **12** to the aortic arch **13**. A snare wire is inserted through the sheath **18** and extended to the aortic arch **13** with a snare loop **21**. In one embodiment, the snare loop has a diameter that is any value or range of values between about 20 to 30 mm; it will be appreciated that the diameter may be less than about 20 mm or greater than about 30 mm.

A second stabilization wire **19** is inserted through the radial artery and guided through the subclavian artery **14** to the aortic arch **13**. In one embodiment, the second stabilization wire has about a 0.014 inch diameter. The stabilization wire **19** is captured by the snare **21** and then pulled into the sheath catheter **18**, as shown in FIG. **3**. In one embodiment, the snare **21** pulls the stabilization wire such that it exits the proximal end of the sheath **18** to form a through-and-through stabilization wire. In one embodiment, a 3 Fr. to 5 Fr. sheath may be used over the 0.014 stabilization wire **19** to reduce slicing and trauma to the arteries the wire is guided through.

A reverse curve catheter **24** with an atraumatic tip is then inserted in parallel with the stabilization wire **19** through the sheath catheter **18**, as shown in FIG. **4**. The reverse curve catheter **24** is used to select the left common carotid artery **15**. A stiff wire **23** is then inserted through the reverse curve catheter **24** to the site of the procedure. In one embodiment, the stiff wire has an approximately 0.035 inch diameter.

Next, the reverse curve catheter **24** is removed, leaving the stiff wire **23** in the area of the procedure and the stabilization wire **19** in place, as shown in FIG. **5**. Both the stiff wire **23** and stabilization wire **19** occupy the large sheath catheter **18**, as shown in FIG. **5**.

A bifurcated catheter having bifurcations **25** and **26** is then advanced over both the stiff wire **23** and the stabilization wire **19** respectively and out of the guide catheter **18**. The large leg (or bifurcation) **25** which contains a procedural catheter tracks along the stiff guide wire **23** into the left common carotid artery **15**. The small leg (or bifurcation) **26** tracks along the stabilization wire **19** coming from the right subclavian/innominate artery. Both legs **25**, **26** have atraumatic tips **28** to reduce trauma, as shown in FIG. **6**.

FIG. **6**A is a cross-sectional view of a portion of the bifurcation catheter within the sheath catheter **18**. The bifurcation catheter includes a common catheter portion that bifurcates into two separate bifurcations or legs **25**, **26** at junction **30**. As shown in FIG. **6**A, each of the bifurcations of legs **25**, **26** include lumens that extend from a distal end of the bifurcation catheter to a proximal end of the bifurcation catheter. As shown in FIG. **6**A, the bifurcated leg **25** is configured to slideably receive the guidewire **23**, and the bifurcated leg **26** is configured to slideably receive the stabilization wire **19**.

Once the bifurcated catheter is in place, the stiff wire and the atraumatic tips are removed and tension is applied to the stabilization wire from both ends to stabilize and position the operational end of the bifurcated catheter, as shown in FIG. **7**.

The bifurcated catheter is now ready for stenting or other procedures in the left internal carotid artery **16**.

FIG. **8**A illustrates the process **800**A described above with reference to FIGS. **2-7**.

The process **800**A begins by inserting a sheath catheter **18** catheter through the groin access and guided using radiographic imaging using the opaque ring **20** at its distal end through the descending aorta **12** to a location in the aortic arch **13** suitable for access into the left common carotid artery **15** (block S**801**A).

The process **800**A continues by inserting and advancing a snare wire through the sheath catheter **18** and out its distal end into the aortic arch **13** (block S**802**A).

The process **800**A continues by inserting a second stabilization guide wire **19** through the radial artery and guiding it through the right subclavian artery **14** to the aortic arch **13** (block S**803**A).

The process **800**A continues by using the snare loop **21** of the snare wire to capture the guide wire **19** and pull it through the sheath catheter **18** to its proximal end to provide an end-to-end stabilization wire over which tensions can be applied (block S**804**A).

The process **800**A continues by advancing a reverse curve catheter **24** up the lumen of the sheath catheter **18** and into the left common carotid artery **15**, again using the opaque ring **25** at its distal end (block S**805**A).

The process **800**A continues by advancing a reasonably stiff guide wire **23** up the reverse curve catheter **24** and into the left common carotid artery **15** to the location of the procedure near the left internal carotid artery **16** (block S**806**A).

The process **800**A continues by removing the reverse curve catheter **24**, leaving the stabilization wire **19** and the stiff guide wire **23** in place, both occupying the lumen of the sheath catheter **18** (block S**807**A).

The process **800**A continues by inserting a bifurcated catheter having a main operational leg **25** over the stiff guide wire **23** and having a stabilization leg **26** over the stabilization wire **19** (block S**808**A).

The process **800**A continues by advancing the bifurcated catheter having atraumatic tips **28** on the end of the main operational catheter leg **25** to the aortic arch **13** through the sheath catheter **18** (block S**809**A).

The process **800**A continues by advancing the main operational leg **25** to the location of the procedure by advancing the main operational catheter leg **25** over the stiff wire **23** (block S**810**A).

The process **800**A continues by extending the second leg **26** of the bifurcated catheter over the stabilization wire **19** through the innominate and the subclavian artery **14** (block S**811**A).

The process **800**A continues by removing the stiff wire **23** and the atraumatic tips **28** and applying tension to the stabilization wire **19** to stabilize the working lumen leg **25** at just below the left internal carotid artery **16** (block S**812**A).

The process continues by performing any treatment procedure, including stenting of the left internal carotid artery **16**, through the main operational catheter leg **25** (block S**813**A).

In another embodiment, the bifurcated catheter accommodates the snare catheter in the secondary lumen. In this embodiment, one leg **25** of the bifurcated catheter is used as the procedural catheter and the other leg of the bifurcated catheter **26** is used initially to send in the snare loop **21** and capture the stabilization wire **19**. A reverse curve catheter **24** is sent through the procedural leg **25** of the bifurcated catheter into the LCCA **15** or RCCA and the stiff guide wire **23** is placed at the location of the procedure site. The second leg of the bifurcated catheter already at the aortic arch **13** is equipped with an atraumatic tip **28** and guided along the wire **23** to the location of the procedure. At the same time, the first leg **26** of the bifurcated catheter is extended to cover the stabilization wire **19** into the subclavian artery **15**. The atraumatic tip **28** and the stiff wire **23** are then removed and the second leg **25** of the bifurcated catheter is ready for the next treatment steps at the site, including stenting or other procedures. This embodiment is further described with reference to FIGS. **2-7** and FIG. **8**B.

In this embodiment, a bifurcated catheter is inserted with the main sheath catheter. In this embodiment, the bifurcated catheter has two chambers therein, one for the procedure and the second chamber for the snare catheter, snare loop/wire, and stabilization wire. This enables passing a snare catheter, snare loop/wire and stabilization wire all through a second chamber/branch of the bifurcated catheter when it is at the apex of the curve of the aortic arch similar to the process described earlier. The process is described below with reference to FIGS. **2-7** and flow chart **800***b* of FIG. **8**B.

FIG. **2** illustrates the distal end of sheath catheter device **18**, showing the distal end **20** of the device percutaneously inserted and advanced through the descending thoracic aorta **12** to the aortic arch **13**. The bifurcated catheter (not shown) is inserted with the sheath catheter and advanced to the aortic arch **13**. A snare wire with a 20 to 30 mm snare is shown extended from the sheath catheter in FIG. **2**. In this embodiment, the snare is within the smaller chamber of the bifurcated catheter within the sheath catheter. The snare captures a stabilization wire **19** that is extended into the aortic arch **13** from the right subclavian artery (RSA) **14**, as shown in FIG. **2**. FIG. **2** further shows the ascending aorta **11**, the LCCA **15**, the left internal carotid artery **16** and the heart **50**.

FIG. **3** shows the snare being tightened **22**. In this embodiment, the snared stabilization wire **19** is pulled into the smaller lumen of the bifurcated catheter (not shown) and to the proximal end of the same to provide and end-to-end stabilization for the procedural catheter.

FIG. **4** shows a reverse curve catheter **24** such as a Simmons catheter with a stiff wire **23** being extended from the sheath catheter **18**. The reverse curve catheter **24** is extended through the second, larger chamber of the bifurcated catheter into the CCA **15** and advanced to the site of the procedure at just below the left internal carotid artery **16**.

The left carotid artery is shown in the figures but it is not meant to be limiting as procedures in both right and left carotid can be addressed with this implementation. Also the carotid artery may be selected with the same reverse guide catheter and a softer guidewire. Once selection has occurred the softer guidewire may be exchanged for the stiffer guidewire.

FIG. **5** shows the stiff wire/guide wire **23** being left at the intended site of the procedure after removal of the reverse catheter.

FIG. **6** shows the bifurcated catheter being advanced with the large lumen **25** over the stiff wire **23** to the site of the procedure and the small lumen **26** over the stabilization wire **19**. An atraumatic tip is used to reduce trauma to the artery during this catheter advance.

FIG. **7** shows the catheter **25** with the wire and the atraumatic tips removed and ready for the procedure. Stabilization for the process catheter is provided by applying tension to the stabilization wire **19**, to stabilize and fix the location of the sheath catheter and the position of the bifurcation.

FIG. **8**B illustrates a process **800**B for stabilizing and fixing the location of the sheath catheter and the position of the bifurcation catheter in accordance with one embodiment of the invention.

The process **800**B begins by inserting a guide wire **23** through the femoral artery percutaneously (block S**801**B).

The process **800**B continues by advancing the guide wire **23** through the descending thoracic aorta **12** to the aortic arch **13** using radiographic imaging (block S**802**B).

The process **800**B continues by inserting a guide or sheath catheter **18** having a platinum ring **20** that is opaque to X-ray at its distal end through the groin access and guiding the sheath catheter **18** through the descending aorta over the guide wire to the aortic arch **13** to a location suitable for access into the left common carotid artery **15** and the left internal carotid artery **16** that is being accessed for the procedure using x-ray fluoroscopy (block S**803**B).

The process **800**B continues by inserting the larger leg of the bifurcated catheter **25** with the smaller leg **26** arranged parallel to it and guiding the bifurcated catheter over the guide wire **23** to the distal edge **20** of the sheath catheter **18** (block S**804**B).

The process **800**B continues by inserting a stabilization guide wire **19** through the brachial artery preferably using a micro sheath and advancing the stabilization guide wire **19** through the right subclavian artery **14** into the aortic arch **13** (block S**805**B).

The process **800**B continues by extending a second segment of the stabilization guide wire having a snare **21** at its distal end out of the smaller leg **26** of the bifurcated catheter to capture the stabilization wire **19** from the subclavian artery and pull it through the smaller leg of the bifurcated catheter and out to its proximal end providing an end to end stabilization wire for stabilizing the sheath and the bifurcated catheter (block S**806**B).

The process **800**B continues by advancing a reverse guide catheter **24** through the tortuous connection of the left common carotid artery **15** to the aorta at the aortic arch **13** over a reasonably stiff wire **23** up the working lumen of the larger leg of the bifurcated catheter through the left common carotid artery **15** just below the left internal carotid artery **16** where the procedure is to be carried out (block S**807**B).

The process **800**B continues by removing the reverse guide catheter **24** and leaving the stiff guide wire **23** in place as a guide to the bifurcated catheter (block S**808**).

The process **800**B continues by advancing the bifurcated catheter out of the guide catheter, the large leg **25** of the bifurcated catheter tracking along the stiff guide wire **23** into the left common carotid artery **15** and the small leg **26** tracking along the guide wire **19** coming from the right subclavian/innominate artery (block S**809**).

The process **800**B continues by removing the guide wire **23** and the atraumatic tips **28** and applying tension to the stabilization wire **19** to stabilize the main catheter leg **25** extending to just below the left internal carotid artery **16** (block S**810**).

The process **800**B continues by performing a treatment procedure, such as stenting or other procedures as needed, at the treatment site (block S**811**).

FIGS. **9** to **15** and FIG. **16** illustrate another embodiment of the invention in which a modified snare bifurcated sheath with a side hole is used instead of the bifurcated catheter to provide stability to the procedural catheter used for stenting and other procedures in the carotid arteries. In this embodiment, the snare loop is inserted through the subclavian artery to capture the snare wire and provide a through-and-through capability for stabilization of the procedural catheter. In some embodiments, the snare loop is inserted through the subclavian artery via a right radial or brachial artery access.

FIG. **9** shows a snare wire **19** having a snare loop at its distal end inserted through the radial artery using a sheath **52** extended through the right subclavian artery **14** into the aortic arch **13**. In one embodiment, the sheath **52** is a Fr 5 sheath. In one embodiment, the snare loop **51** has a 30 to 40 mm diameter. A reverse curve catheter **53**, such as a Simmons catheter, is inserted through the groin access and guided through the descending aorta **12** to select the left common carotid artery **15** (it can also be used to select the right carotid artery). In one embodiment, the reverse curve catheter **53** is a Fr. 5 catheter.

FIG. **10** further shows a secondary stabilization wire **55** that is inserted from the proximal end of the reverse curve catheter **53** and exited out of a hole **54** on the side of the catheter **53** at the location at the apex of the curve of the aortic arch **13**. In one embodiment, the secondary stabilization wire has a 0.014 diameter.

FIG. **11** shows the stabilization wire **55** being snared by the snare **56** to provide a tensionable stabilization capability comprising the snare **56** from the sheath catheter **52** coming from the right subclavian artery and the snared wire **55** coming from the reverse curve catheter **53**.

FIG. **12** further shows a stiff guide wire **57** being extended from the reverse catheter **53** into the left common carotid artery **15** and below the left internal carotid artery **16** where the procedure is expected to be carried out once the tensionable stabilization is established.

FIG. **13** shows the withdrawal of the reverse catheter **53** leaving both the snare **56**, snared stabilization wire **55**, and the stiff guide wire **57** into the left common carotid artery **15**, and below the left internal carotid artery **16**.

FIG. **14** shows a bifurcated sheath catheter **58** having two chambers—one for the stabilization wire and the other for the process catheter with an atraumatic dilator tip **59**, being guided over the stiff guide wire and the stabilization wire **55**, which exits the sheath through a hole **60**, in the sheath catheter **58**. In one embodiment, the bifurcated sheath catheter **58** is a Fr.6 or Fr.7 sized catheter.

FIG. **15** shows the sheath catheter **58** with the stiff wire and atraumatic tip removed with the snared stabilization wire **55**, forming an end-to-end wire enabling stabilization tension to be applied to stabilize the sheath catheter **58** extending into the left internal carotid artery **16** for inserting the procedural catheter for stenting and other procedures from the aortic arch **13**.

In yet another embodiment, the initial sheath catheter may have two lumens, one for the support and stabilization wire and a second as the operational catheter. Further, the operational catheter may be made with a softer operational leg at its distal end which can be used as a reverse curve guiding catheter as well. By combining the application capabilities of such a catheter, it is possible to reduce the number of catheters used and hence the number of steps needed for set up and completion of the procedure.

FIG. **16** is flow chart illustrating a process **1600** according to another embodiment of the invention.

The process **1600** begins by inserting a wire with a snare **51** through a sheath **52** that is inserted through the radial artery and directed through the right subclavian artery **14** such that the snare is in the aortic arch **13** (block S**1601**).

The process **1600** continues by percutaneously inserting and advancing a reverse curve catheter **53** up the femoral artery into the descending thoracic aorta **12** into the left common carotid artery **15** using radiographic imaging (block S**1602**).

The process **1600** continues by inserting a secondary stabilization wire **55** into the reverse curve catheter **53** at the proximal end and exited from a hole **56** near the distal end of the reverse curve catheter at the aortic arch **13** to be snared by the snare **51** from the subclavian artery **14** (block S**1603**).

The process **1600** continues by snaring the stabilization wire **55** to provide an end to end stabilization (**55**) to the catheter, and extending a stiff guide wire **57** through the

reverse curve catheter **53** into the left common carotid artery **15** to the location of the procedure (block S**1604**).

The process **1600** continues by removing the reverse curve catheter **53**, leaving both the stabilization wire **55** and the stiff guide wire **57** in place in the arteries (block S**1605**).

The process **1600** continues by advancing a bifurcated sheath catheter **58** having two partitions (one for the stabilization wire **55** with a side hole **60** near the distal end and another with a dilator tip **59** for the guide wire **57**) over the two wires into position such that the sheath catheter for process **58** is extended into the carotid artery **16** while the stabilization wire **55** through the hole **60** in the bifurcated sheath catheter **58** extends from the proximal end of the sheath catheter **58** through the hole **60**, through the aortic arch **13** and subclavian artery **14** to provide a through and through capability to provide tension and stabilization to the operating catheter **58** (block S**1606**).

The process **1600** continues by extending the sheath catheter into the left internal carotid artery **16** to the location of the procedure (block S**1607**).

The process **1600** continues by removing the stiff guide wire **57** and the atraumatic dilator tip **58** and tensioning the stabilization wire **55** to provide stability to the sheath catheter **58** (block S**1608**).

The process **1600** continues by inserting the catheter for the procedure through the main chamber of the sheath **58** to the location of the procedure in the left internal carotid artery **16** (block S**1609**).

The process **1600** continues by performing a stenting or other procedure at the treatment site (block S**1610**).

In another embodiment, a reverse curve catheter with a lumen sufficiently large for stenting instead of a sheath catheter may be used. In this embodiment, the reverse curve catheter having two lumens, one large procedural lumen and the other a smaller stabilization lumen, is used to select the carotid artery. A secondary wire is inserted in the reverse curve catheter (through the stabilization lumen) and out of a hole in the reverse curve catheter at the location of the arch. This secondary wire is then captured by a snare wire with a loop that is extended out of a protective sheath extended through the subclavian artery. The carotid stenting procedure can now proceed in the standard way using the procedural lumen of the reverse curve catheter since the reverse curve guiding catheter itself is stabilized and is usable for procedure.

Though the examples provide show specific access points for the procedural catheter and the stabilization wires it is not meant to be limiting. There may be other scenarios possible. For example, in an alternate scenario, the main access is through the right radial artery and the stabilization wire or snare is introduced from the groin access or even the left radial artery access. Also the main access may be from the left radial artery with the stabilization wire or snare still comes out through the right subclavian artery.

As will be understood by those familiar with the art, the invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. Likewise, the particular naming and division of the members, features, attributes, and other aspects are not mandatory or significant, and the mechanisms that implement the invention or its features may have different structural construct, names, and divisions. Accordingly, the disclosure of the invention is intended to be illustrative, but not limiting, of the scope of the invention.

While the invention has been described in terms of several embodiments, those of ordinary skill in the art will recognize that the invention is not limited to the embodiments described, but can be practiced with modification and alteration within the spirit and scope of the appended claims. The description is thus to be regarded as illustrative instead of limiting. There are numerous other variations to different aspects of the invention described above, which in the interest of conciseness have not been provided in detail. Accordingly, other embodiments are within the scope of the claims.

The invention has been described in relation to particular examples, which are intended in all respects to be illustrative rather than restrictive. Those skilled in the art will appreciate that many different combinations will be suitable for practicing the present invention. Other implementations of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. Various aspects and/or components of the described embodiments may be used singly or in any combination. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

What is claimed is:

1. A carotid percutaneous intervention system configured to provide end to end stabilization and support for a procedural catheter using a bifurcated catheter, the system comprising:

a sheath catheter percutaneously insertable through a femoral artery access and positionable in an aortic arch, the sheath catheter comprising a proximal end and a distal end, wherein the proximal end is located at the femoral artery access;

a stabilization wire, comprising a proximal end and a distal end, insertable through a percutaneous radial artery access and deliverable to the aortic arch, wherein the stabilization wire is further extendable through the sheath catheter and out of the proximal end of the sheath catheter at the femoral artery access, wherein the proximal end of the stabilization wire is at the percutaneous radial artery access and the distal end of the stabilization wire is at the femoral artery access; and

wherein the stabilization wire provides end to end stabilization to a procedural lumen of the bifurcated catheter, during access of a carotid artery, through the procedural lumen of the bifurcated catheter, by the procedural catheter and during subsequent procedures within the carotid artery, by application of tension on the stabilization wire between the proximal end at the radial artery access and the distal end at the femoral artery access; wherein a first leg of the bifurcated catheter is deliverable over the guide wire to the treatment site; and a second leg of the bifurcated catheter is positionable over the stabilization wire, wherein the first leg and the second leg join with a common catheter portion at a junction, and wherein the junction is positionable within the aortic arch below an ostium of the carotid artery; wherein a distal tip of the first leg and a distal tip of the second leg comprise atraumatic tips to reduce trauma to the arteries that are accessed, the first leg over the guide wire and the second leg over the stabilization wire.

2. The system of claim **1**, further comprising:

a reverse curve catheter insertable through the sheath catheter parallel to the stabilization wire, wherein the reverse curve catheter is configured to access the carotid artery through the aortic arch and an ostium of the carotid artery to further enable insertion of the guide wire.

3. The system of claim 2, further comprising:

the guide wire insertable through the reverse curve catheter, wherein the guide wire is further configured to access the carotid artery and a treatment site.

4. The system of claim 1, wherein the first leg of the bifurcated catheter is stabilized at the treatment sited by applying end to end tension to the stabilization wire.

5. The system of claim 1, further comprising:

a bifurcated catheter having a proximal end and a distal end, wherein the bifurcated catheter comprises a common catheter portion comprising a lumen at the proximal end and a bifurcation comprising a first leg and a second leg at the distal end, and wherein the first leg comprises a first lumen that is larger than a second lumen in the second leg, wherein the second leg of the bifurcated catheter is pre-loaded into the sheath catheter, wherein the snare wire is passed through the second lumen of the second leg of the bifurcated catheter to snare the stabilization wire and pull it through the second lumen in the second leg; and

a reverse curve catheter insertable through the lumen of the common catheter portion and the first lumen of the first leg of the bifurcated catheter to access the carotid artery, wherein stabilization is provided by the stabilization wire that enable stable access to the ostium of the carotid artery and a site of the procedure.

6. The system of claim 5, wherein the first lumen comprises a procedural lumen and wherein the second lumen comprises a stabilization lumen.

7. The system of claim 6, wherein the procedural lumen extends from the proximal end of the bifurcated catheter to the distal end of the bifurcated catheter through the lumen of the common catheter portion and the first lumen of the first leg, and wherein the stabilization lumen extends from the proximal end of the bifurcated catheter to the distal end of the bifurcated catheter through the lumen of the common catheter portion to the second lumen of the second leg.

8. The system of claim 7, wherein the stabilization lumen is for slideably receiving a stabilization catheter or the stabilization wire.

9. The system of claim 1, further comprising:

the procedural catheter insertable through the proximal end of the bifurcated catheter and extending through the first leg of the bifurcated catheter to access the treatment site.

10. The system of claim 1, wherein end-to-end tension is applicable to the stabilization wire between the proximal end and the distal end to stabilize the first procedural lumen of the bifurcated catheter and improve pushability of the procedural catheter while accessing the carotid artery and the treatment site.

11. A carotid percutaneous intervention system comprising:

a sheath catheter percutaneously insertable through a first percutaneous access and positionable in a location at an ostium of a vessel where a procedure is to be performed;

a first wire having a proximal end and a distal end, the first wire comprising a snare at the distal end, wherein the wire is percutaneously inserted into the sheath catheter through the first percutaneous access and positionable at the ostium of the vessel;

a stabilization wire having a proximal end and a distal end, the stabilization wire insertable through a second percutaneous access and guidable to the ostium of the vessel, the distal end of the stabilization wire capturable by the snare and pullable to the first percutaneous access through the sheath catheter;

a bifurcated catheter having a bifurcation comprising an arm with a reverse curve catheter feature and a hole for the stabilization wire at a distal end of the bifurcated catheter, the bifurcated catheter advanceable through the sheath from the first percutaneous access to the location of the ostium of the vessel where the procedure is to be carried out, the bifurcated catheter advanceable over the stabilization wire through the hole at the distal end of the bifurcated catheter;

when the stabilization wire is configured to be pulled by the snare to the first percutaneous access such that the stabilization wire extends out of the first and second percutaneous accesses, the stabilization wire is configured to provide end to end stabilization and pushability to the reverse curve catheter by application of a tension to the proximal end and distal end of the stabilization wire.

12. The system of claim 11, further comprising a stiff guidewire having a proximal end and a distal end, the stiff guidewire insertable through the reverse curve catheter such that the distal end of the stiff guidewire is positionable at the treatment site.

13. The system of claim 12, wherein the reverse curve catheter feature is removable following delivery of the stiff guidewire in the carotid artery.

14. The system of claim 12, further comprising:

a procedural catheter insertable through the bifurcated catheter over the stiff guidewire into the location of the procedure within the vessel through the ostium of the vessel.

15. The system of claim 14, wherein the bifurcation catheter comprises:

a common catheter portion at a proximal end of the bifurcation catheter, the common catheter portion comprising a lumen;

a first leg at a distal end of the bifurcation catheter and comprising a first lumen, wherein the first leg is deliverable over the stiff guidewire to a treatment site; and

a second leg at a distal end of the bifurcation catheter and comprising a second lumen, wherein the second lumen is smaller than the first lumen, and wherein the second leg is positionable over the stabilization wire,

wherein the first leg and the second leg join with the common catheter portion at a junction, and wherein the junction is positionable at the location at the ostium of the vessel where the procedure is to be carried out.

16. The system of claim 15, wherein the junction is Y-shaped.

17. The system of claim 15, wherein the first lumen comprises a procedural lumen and the second lumen comprises a stabilization lumen.

18. The system of claim 17, further comprising:

a procedural catheter insertable through the procedural lumen of the bifurcated catheter after removal of the stiff guidewire.

19. The system of claim 11, wherein the hole comprises a second lumen.

20. A bifurcated catheter for use in a percutaneous intervention system comprising:

a body comprising a proximal end and a distal end, wherein the body comprises:

a common catheter portion at the proximal end, the common catheter portion comprising a lumen;

a bifurcation having a first leg and a second leg at the distal end;

the first leg at the distal end, the first leg comprising a first lumen; and

the second leg at a distal end, the second leg comprising a second lumen, the first lumen being larger than the second lumen, the first lumen being of a size to carry a procedural catheter and the second lumen being of a size to only carry a stabilization wire;

wherein the first leg and the second leg join with the common catheter portion at a junction; and

wherein the first leg of the bifurcated catheter is configured to be stabilized by application of a tension to the stabilization wire between a proximal end of the stabilization wire at a first percutaneous access and a distal end at a second percutaneous access of the stabilization wire when the stabilization wire is inserted in the second lumen; wherein the body comprises a procedural lumen and a stabilization lumen that extend from the proximal end to the distal end of the body, the procedural lumen of the body comprising the first lumen and the stabilization lumen of the body comprising the second lumen; wherein the procedural lumen extends from the proximal end through the common catheter to the distal end through the first leg, and wherein the stabilization lumen extends from the proximal end through the common catheter to the distal end through the second leg.

21. The system bifurcated catheter of claim **20**, wherein the junction is Y-shaped.

22. The bifurcated catheter of claim **20**, wherein the stabilization lumen is configured to provide stabilization and pushability to the procedural catheter through the first lumen of the bifurcated catheter.

23. The bifurcated catheter of claim **20**, wherein a distal tip of the first leg and a distal tip of the second leg comprise atraumatic tips.

24. The bifurcated catheter of claim **20**, wherein the bifurcated catheter is configured to provide stability and pushability to the procedural catheter and stabilization wire, by applying tension on the stabilization wire, thereby protecting the arterial system including the artery, an ostium of the vessel and the vessel itself during manipulation of a guide wire and procedural catheter or procedural equipment.

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